DE NOVO CLASSIFICATION REQUEST FOR

Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Implantable post-surgical kinematic measurement knee device. An implantable post-surgical kinematic measurement knee device is a device that provides objective kinematic data after total knee arthroplasty surgery. The kinematic data provided by the device are used as an adjunct to other physiological parameter measurement tools utilized during the course of patient monitoring and treatment post-surgery.

NEW REGULATION NUMBER: 21 CFR 888.3600

CLASSIFICATION: Class II

PRODUCT CODE: QPP

BACKGROUND

DEVICE NAME: Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System

SUBMISSION NUMBER: DEN200064

DATE DE NOVO RECEIVED: October 19, 2020

SPONSOR INFORMATION:

Canary Medical, Inc.
2150 Western Parkway, Suite 202
Vancouver, BC V6T 1V6
Canada

INDICATIONS FOR USE

The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System is intended to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58mm sized tibial stem extension.

The objective kinematic data generated by the CTE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

The CTE with CHIRP System is compatible with Zimmer Persona® Personalized Knee System.

LIMITATIONS

The sale, distribution, and use of the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System are restricted to prescription use in accordance with 21 CFR 801.109.

The outputted data from the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System are not intended to be utilized for clinical decision-making and has not been evaluated for such a purpose.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

For a complete description of the device system components and subsystems, please refer to the accompanying labeling for additional details.

Implant Description:
The Canary Tibial Extension is a physical implant component that is attached to the Zimmer Biomet Persona® tibial baseplate (K113369) to form the patient's tibial knee prosthesis. Like a traditional tibial extension, the CTE provides additional stability to the replacement knee joint. In addition, the software and electronics embedded within the CTE collect the patient's functional movement and gait parameter information post-surgery. The CTE is provided sterile via Ethylene Oxide (EtO).

The CHIRP system collects unprocessed 3D accelerometer and 3D gyroscopic sensor data over the course of a day. The following table displays the gait and activity metrics generated:

Table 1: Gait Parameters Collected by the CTE with CHIRP System

PARAMETER	DESCRIPTION	UNITS	AVAILABLE TO WHOM?
Walking Speed	Mean sagittal plane distance walked per unit time. Directly calculated from cadence and stride length for each gait cycle.	meters per second/s	Physician Patient

Cadence	Mean steps per minute. Derived from two consecutive peak angular velocities.	steps per minute	Patient
Stride length	Mean distance traveled during one gait cycle.	meters	Physician Patient
Knee ROM	Mean sagittal plane functional knee joint range of motion. Difference between maximum and minimum knee joint flexion.	degrees	Physician Patient
Tibia ROM	Mean sagittal plane range of motion of the tibia with respect to the floor. Difference between the minimum and maximum tibia to floor angle.	degrees	Physician
Step Count	Number of steps taken during a Sampling Day.	steps	Physician Patient
Distance	Distance traveled. Calculated from step count and stride length	meters	Physician Patient

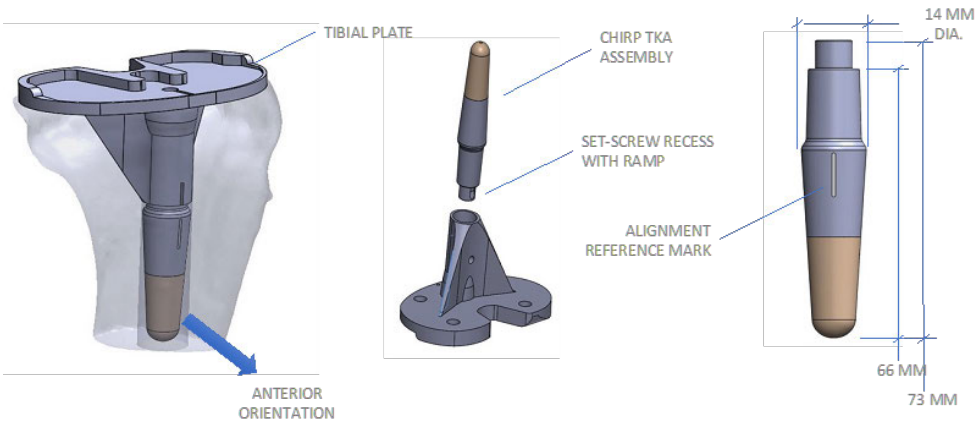

Figure 1 (from left to right): a) CTE implant attached to tibial baseplate; b) alternate view of CTE assembly and tibial base plate; and c) CTE implant with dimensional attributes

The electronic and other unique elements incorporated within the CTE implant include an antenna, X-ray ID, printed circuit assembly, three-axis gyroscope, three-axis accelerometer, and a Lithium Carbon Mono-Fluoride (CFx) battery. To allow for wireless transmission of kinematic data, the nose cone is manufactured from polyether ether ketone (PEEK). All active electronics and the battery are encapsulated within a hermetically sealed titanium enclosure. The antenna is encapsulated by the PEEK nose cone and epoxy backfill, both of which are electrically non-conductive. The antenna is the only electrically active component of the CTE outside the hermetic assembly and, under normal operating conditions, is insulated by the epoxy backfill and PEEK nose cone from interacting electrically with surrounding tissue.

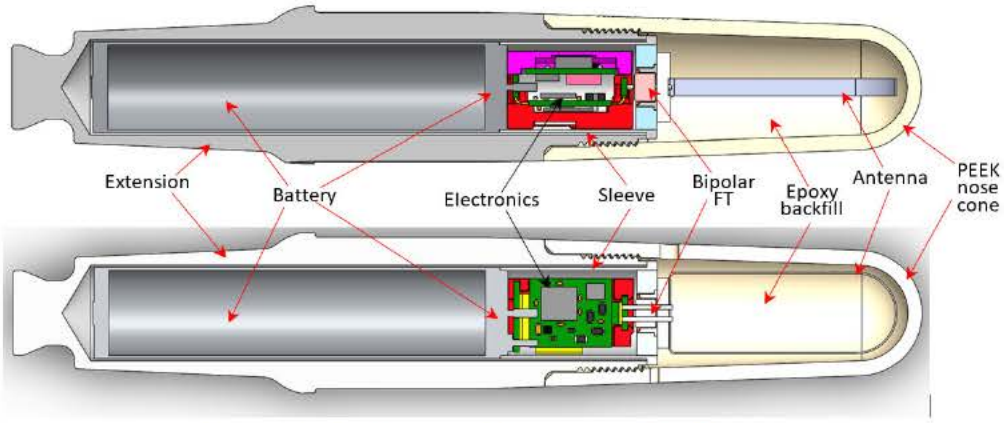

Figure 2: CTE assembly cross-sectional views

The CTE implant can store up to 30 days of data. If the CTE implant is unable to connect to the Home Base Station for an extended period, the full amount of data will be uploaded to the Canary Cloud once the patient's CTE connects to its Home Base Station. If there is no connection for periods greater than 30 days, new data will overwrite the oldest data until a connection to the patient's Home Base Station and the Canary Cloud is made. The CTE implant has been programmed to collect data using the schedule provided in the table below. This sampling schedule is controlled by firmware on the CTE which is loaded during the manufacturing process. When the CTE is not sampling, it is in a low power mode to conserve battery power.

Table 2: Sampling rate of CTE with CHIRP System

Time Period	Sampling
Day 0 (day of surgery) to Day 1	No sampling
Day 2 to Day 365	Daily
Year 2	36 consecutive Days/Quarter
Years 3 and beyond	36 consecutive days commencing on the anniversary of the patient's surgery date

When the CTE is not sampling after it has been implanted and activated, the CTE remains in a state of ultra-low power deep sleep prior to implantation to preserve battery power. Prior to implantation, the CTE remains constantly in a state of deep sleep until "woken up" by the OR Base Station the day of implantation.

Base Station Description:

The CTE with CHIRP system is composed of external base station units with embedded firmware that facilitate communication with the CTE implant. The main function of the base station units is to act as a conduit to receive and transmit encrypted raw kinematic data from the CTE to the Cloud Based software system.

All communication between the Base Station units and the CTE implant employs a unique communication protocol, with each CTE implant having a unique radio ID that is assigned to it

in manufacturing. Base stations can communicate with only one CTE at a time using the unique radio ID. The communication between base stations and CTE implant is also encrypted (both the data payload and messaging) with the unique encryption key assignment during the manufacture of the CTE. Communication integrity and data integrity checks are applied on the data received at both ends.

The Operating Room (OR) Base Station (BS1) subsystem consists of a laptop computer with the customized OR Application (OR App) software to initialize the CTE implant and record implant and procedural information, an OR base station unit, a bar code reader to incorporate TKA component and CTE serial number information, and USB cables to attach the OR base station unit and bar code reader to the computer. The surgical team uses the BS1 during the TKA surgery to register the patient and activate the CTE implant so that it will begin collecting data after the patient's surgery. The hardware functions are limited to assisting the following software functions: electronic transfer, storage, or display of medical device data.

After the TKA is implanted, the OR application is used to scan the barcodes on the labels of the CTE and other implanted TKA components; these data can also be manually entered. This information can then be submitted by the OR App to the Canary Cloud. This action associates the particular CTE with the previously registered patient in the Canary Cloud. The action of associating the CTE with the patient also enables the Home Base station to recognize the CTE when the patient returns home, thus enabling upload of kinematic data from the CTE to the Cloud without patient intervention.

The Home Base Station (BS2) subsystem is located in the patient's home, is set up by the patient prior to the date of surgery, and is used to transmit patient's gait and activity information collected by the CTE. BS2 consists of a Home Base Station unit, a USB power and data cable, and a power adapter. These items are used in concert with a USB-enabled personal computer and the patient's home wireless Internet connection. The Home Base Station can store up to 45 days of CTE-transmitted data if it is not able to connect to the Cloud but is able to communicate with the implant locally.

The OR Base Station variant does not have wireless capability as no connectivity is needed in the operating room for functionality. The Home Base Station unit includes Wi-Fi capability to transfer data from the CTE to the Canary Cloud.

Canary Medical Cloud Data Management Platform (CDMP or "Cloud"):
The Cloud subsystem is intended to receive and store all healthcare professional (HCP) and patient data for pre-operative, day of operation, and post-operation activities, including unprocessed, patient kinematic data from the CTE implant. The post-operation processed, patient Canary Medical Gait Parameter (CMGP) data will be used by HCPs to monitor the patient's post-TKA procedure function as an adjunct to other physiological parameter measurement tools. The Cloud is accessible through a browser-based web application.

Manual Instruments and Accessories:
All CTE with CHIRP System Surgical Instrumentation is supplied non-sterile in an instrument tray:

- Impaction Sleeve: A reusable instrument used to assist in attaching the CTE implant to the Zimmer Biomet Persona® Tibial Plate. The Impaction Sleeve protects the implant's electronic components from impaction forces that occur during assembly.
- Canary Tibia Cut Guide (5 DEGREE – L/R): Used for tibia preparation when implanting a Persona Primary Knee with a Canary Tibial Extension (CTE) Implant.
- Canary Drill Bit: Used to create the cavity in the patient's tibial intramedullary (IM) canal to fit the CTE implant and cement mantle.
- CTE Provisional: The Persona Tibial Keel length ranges from 23.4 mm to 40 mm. The Canary Tibial Extension adds 28 mm to the length of the tibial keel nominally when assembled. This CTE Provisional is used to test the depth of the drilled intramedullary hole to ensure the fit of the CTE implant within the patient's anatomy prior to CTE implantation.
- CTE Template: The CTE 14mm x 58mm X-Ray Template is a surgical instrument used to assist the surgeon during preoperative planning. The CTE Template will be used to assess the patient anatomy for the Zimmer Biomet Persona Tibia Baseplate with Canary Tibial Extension construct sizing. It is composed of acetate and is used as an overlay to the patient's X-ray image; therefore, it has no contact with the patient.

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SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The CTE with CHIRP system is manufactured from the following patient-contacting materials:

Table 3: Manufactured Materials of Patient-Contacting Device Components

Description	Material	Direct Patient Contact	Contact Duration
Implant	Victrex 450 G Natural PEEK per ASTM F2026; Loctite M-31CL Epoxy; Grade 23 Ti-6AI-4V per ASTM F136	Yes	Permanent (>30 d)
Patient-contacting Instruments	17-4 PH or 455 Stainless Steel	Yes	Limited (≤24 h)

Biocompatibility evaluation has been completed according to 2020 FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."

For the permanent, implant, the following table shows the biocompatibility testing performed and the results, which were acceptable for a permanent implant in contact with bone/tissue:

Table 4: Biocompatibility Testing Performed

Test Description	Result
Cytotoxicity (MEM Elution per ISO 10993-5)	Non-cytotoxic
Sensitization (Guinea Pig Maximization test per ISO 10993-10)	Non-Sensitizer
Irritation (Intracutaneous Injection per ISO 10993-10)	Non-Irritant
Material Mediated Pyrogenicity in rabbits (USP <161>)	Non-Pyrogenic
Bacterial Endotoxin (BET, LAL testing per USP <161>)	Non-Pyrogenic
Acute/Subacute/Subchronic/Chronic Systemic Toxicity, Genotoxicity and Carcinogenicity (addressed through chemical characterization and toxicological risk assessment per ISO 10993-18/ISO 10993-17	Non-systemically toxic/genotoxic/carcinogenic

All other components of the device system are either not patient-contacting or only have transitory contact with skin.

Regarding patient-contacting surgical instruments manufactured with stainless steel, passivation was conducted during the manufacturing process, and no chemicals were added after passivation. Therefore, no additional biocompatibility testing was needed for the patient-contacting surgical instrumentation.

PACKAGING, STERILIZATION, CLEANING, AND SHELF LIFE

CTE Implant

The CTE Implant is a single-use device provided clean and sterile to the end user.

Sterilization methods of the device have been validated in accordance with ISO 11135, "Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices", to ensure a sterility assurance level (SAL) of 10^{-6} before the device is marketed. Bacterial endotoxins testing (BET) was performed to determine that the subject device implant met pyrogen limit specifications. All tested lots passed with a reported value of ≤1 EU/device, meeting the recommended endotoxin limits per ANSI/AAMI ST72:2011 ("Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing").

Accelerated aging to support a 12-month and 24-month shelf life was performed for the EO-sterilized CTE Implant per ASTM F1980, "Standard Guide for Accelerated Aging of Sterile Medical Device Packages." The expiration date of 24 months was verified by

demonstrating package integrity through gross leak, seal strength, and seal integrity of the tray seal packaging per ASTM D4169, "Standard Practice for Performance Testing of Shipping Containers and Systems."

Manual Surgical Instruments

All CTE instruments are provided non-sterile and should be cleaned and sterilized by the end-user prior to use. Steam sterilization methods per ISO17665-1, "Half Cycle Method (Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices)" were validated to ensure a sterility assurance level (SAL) of 10^{-6}.

Manual and automated cleaning methods have been validated to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with AAMI TIR12 ("Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers") and AAMI TIR30 ("A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices"). Validated reprocessing instructions are included in their own separate labeling document.

ELECTROMAGNETIC CAPABILITY, ELECTROMAGNETIC SAFETY, AND WIRELESS

Electromagnetic compatibility and electrical safety testing have been performed in accordance with the following standards:

- IEC 60601-1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility – Requirements and tests;
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability; and
- IEC 60601-1-11:2015 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

The objectives of the series of tests to support electromagnetic compatibility, electrical safety, and wireless communication include the following:

- The CTE shall operate normally following exposure to a simulated electrosurgical environment and shall not exhibit unintentional radiated emissions above recommended limits.
- The CTE shall meet performance requirements related to radiated power, receiver sensitivity, frequency range, channel bandwidth, out-of-band power, and compatibility with Base Station communication.
- The Base Stations shall meet basic electrical operation functions.

- The CTE implant and base stations shall communicate wirelessly on the Medical Implant Communication Service (MICS) at the appropriate frequency.
- The testing shall verify that the CTE does not exhibit unintentional radiated emissions above recommended limits and is immune to electrosurgical equipment.
- The testing shall demonstrate that the CTE meets FCC requirements for emitting devices and to ensure communication signals fall within regulatory limits.
- The testing shall assess the electrical safety and usability of the subject device components in the appropriate use setting.
- The testing shall assess the safety, compatibility, radio frequency, and magnetic immunity of the base station.
- The testing shall evaluate wireless co-existence to demonstrate the device can function with other wireless devices in proximity.

The test results support electromagnetic compatibility, electrical safety, and wireless communication.

MAGNETIC RESONANCE (MR) COMPATIBILITY

To support MR conditional labeling for the CTE implant, the following MR testing was conducted to evaluate device safety and compatibility:

- Magnetically Induced Displacement Force per ASTM F2052-14, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment"
- Magnetically Induced Torque aper ASTM F2213-06, "Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment"
- Radiofrequency (RF) Induced Heatings per ASTM F2182-11a, "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging"
- Image Artifact as per ASTM F2119-07, "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants"

Since the CTE is designed and intended for use with the Zimmer Persona Personalized Knee system, MR evaluation was performed in the following two parts:

1. Functional evaluation of CTE after MR scan
2. Comparison studies of Zimmer Knee assembled with a Zimmer Persona standard tapered stem extension and the CTE extension.

In magnetic field interaction tests, the CTE implant showed a translational attraction (deflection angle of 4.7°) and no torque. In image artifact testing, the maximum image artifact was measure for both spin echo and gradient echo purse sequences in a 3.0T MR scanner and appeared smaller in size in relation to the size and shape of the subject device. In MRI-related heating testing, test results show that, at 1.5T, the RF-induced heating for CTE with tibial plate was 3.8 °C and for the Zimmer Biomet Personal 30mm

Stem Extension with tibial plate was 5.0 °C. At 3T, the RF-induced heating for CTE with tibial plate was 6.3 °C and for the Zimmer Biomet Personal 30mm Stem Extension with tibial plate was 8.1 °C. At both 1.5T and 3T, the RF-induced heating for CTE with tibial plate was less than for Personal 30mm Stem Extension with tibial plate. The CTE implant all functional tests and has demonstrated not to lead to higher RF-induced heating as compared to that from the Zimmer Persona standard tapered stem extension tibia insert. Therefore, the same MRI safety labeling from the Zimmer Persona Personalized Knee system can be applied to the CTE implant.

SOFTWARE AND CYBERSECURITY

The CTE with CHIRP System software documentation and verification testing is based on a Moderate Level of Concern per FDA's guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Failure or latent design flaws of the CTE with CHIRP System could either directly result in death or serious injury to the patient or operator or indirectly result in minor injury to the patient or operator. The device and labeling passed all relevant portions of the testing.

Software Description

The CTE with CHIRP System includes seven (7) software components which accomplish functions and manage communications within and among the CTE with CHIRP subsystems. These components include:

- Canary Cloud Data Management Platform (CDMP) Application, which is a web application for user account management, kinematic data display, and data management;
- Operating Room Application, which performs a variety of functions (CTE implant self-testing, sensor check, patient data upload) in the operating room during the day of surgery;
- Base Station Setup Tool (BSST), which enables Home Base Station connection to the Cloud;
- Canary Medical Gait Parameters (CMGP), which calculates kinematic gait parameters from raw sensor data;
- CTE embedded firmware application, which responds to wakeup commands and status requests and collects and transmits raw accelerometer and gyroscope data; and
- BS1 and BS2 embedded firmware applications that enables Base Station interaction with the CTE implant, operating room computer, and Cloud.

Verification Testing

Software verification testing activities were performed for the software components to verify that the system functions as designed. Testing of the software components occurred at the unit, integration, and system level, as appropriate. Following completion of the verification procedures, all features pertaining to collecting, transmitting, and displaying of kinematic data have passed the testing acceptance criteria.

Revision Level History

The current version of each software/firmware component is as follows:

- CTE firmware: v1.0.2;
- BS1/BS2: v1.1.0;
- Base Station Setup Tool: v1.0.93.0;
- OR Application: v1.3.99.0;
- Cloud Application: v1.0/1.1/1.0; and
- Canary Medical Gait Parameters Application - v1.15.

Cybersecurity

Adequate cybersecurity documentation was provided per recommendations in FDA Guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," including a list of all cybersecurity risks and controls, a traceability matrix linking controls to the risks and testing performed, system diagrams to support threat modeling, a summary describing continuing support and malware-free shipping, and cybersecurity labeling. In addition, a Cybersecurity Bill of Materials (CBOM) was provided.

MEDICAL COMPATIBILITY

Testing or scientific rationale was provided to verify survival and safety of the CTE implant when exposed to anticipated worst-case use conditions of controlled ultrasonic energy and X-ray conditions.

For ultrasonic energy testing, an energy level of (b) (4) was applied, nearly (b) (4) times the required protocol minimum. Also, the ultrasonic energy was applied at (b) (4) different positions along the long axis of each CTE for a total exposure of (b) (4) minutes along each orientation. After completion of each test, each CTE was queried to evaluate operating health of the internal CTE electronics and each CTE was considered passing.

X-ray compatibility testing was verified during cadaver validation testing (see appropriate section in the PERFORMANCE TESTING – BENCH section below), in which the test protocol requires X-ray fluoroscope imaging after implantation of the CTE in human cadaver tibia. Test results from the cadaver testing verified acceptable operating health of the internal CTE electronics.

BATTERY SAFETY AND CHARACTERIZATION TESTING

The CTE implant battery incorporates Lithium Carbon Mono-Fluoride (CFx) chemistry and has a proposed use life of a minimum of 10 years. A summary of battery-related testing results is provided below.

CTE Battery Design Verification

The test objective was to verify design, safety, and electrical performance of the CTE battery. The following technical characteristics were tested: battery capacity; discharge; external and atmospheric pressure; high/low temperature storage; mechanical shock; and shipping and safety. All design verification requirements were met and supports use in implantable applications.

CTE Battery Longevity

The test objective was to verify that the CTE implant design meets battery longevity requirements, which are derived from the design objective that, in a minimum 10-year service life, the CTE will provide at least (b) (4) days of sampling data. The power consumption was calculated based on different scenarios, including radio standby, lowest use idle mode, during wireless data upload, and various sampling modes.

Using the worst-case scenario, the CTE implant demonstrated a minimum service life of greater than 15 years, which exceeds the 10-year CTE service life design requirement.

CTE Battery Short-Circuit Characterization

The test objective is to verify that the implantable battery will not vent even if externally short-circuited. A total of (b) (4) CTE battery cells were evaluated including (b) (4) fresh fully charged cells (beginning of life, "BOL") and (b) (4) discharged cells (end of life, "EOL"). Prior to any testing, the mass and open-circuit voltage of each cell was measured. Prior to application of the external short circuit, each cell to be tested was heated for a period necessary to reach a homogeneous stabilized temperature of (b) (4) °C, measured on the external case. Then, the cell or battery at (b) (4) °C was subjected to (b) (4) short circuit condition with a total external resistance of less than (b) (4) ohm. The short circuit condition was continued for at least (b) (4) after the cell or battery external case temperature returned to (b) (4) °C. During the short circuit condition, external case temperature was monitored with a maximum allowable level of (b) (4) ºC. All cells passed the maximum temperature criteria with a maximum observed temperature of (b) (4) ºC. Each cell was then visually inspected for any signs of venting or leakage consistent with (b) (4) and none was observed. Finally, the post-short-circuit mass of each cell was measured with a maximum permissible change of (b) (4) from pre-test mass, and all cells passed, further indicating no venting or leakage.

Thermal Safety

The test objective was to verify that the temperature rise measured at the polymethyl methacrylate (PMMA)/tissue interface following a CTE battery short does not rise above the defined acceptance criterion. (b) (4) configurations of a thermal phantom were developed to approximate (b) (4) and (b) (4) percentile human anatomy, which represent the anatomical boundary conditions for temperature increase scenarios. (b) (4) assemblies were tested in the (b) (4) percentile human anatomy phantom and (b) (4) additional units were tested in the (b) (4) percentile human anatomy phantom for a total of (b) (4) test samples. Thermistors were placed in a plane previously determined to be that of worst-case thermal exposure and were cast in place at the tissue-PMMA interface in a tissue-analogue which represents the worst-case thermal properties (i.e. most insulative). The

battery was then shorted, and temperature was measured for either (b) (4) or until the temperature from all thermistors had decreased to less than (b) (4) °C of their temperatures recorded immediately prior to beginning the test. The values obtained were then substituted into the CEM43 (Cumulative Equivalent Minutes at 43°C) equation in section 17.1 of ISO 14708-3 and compared to the required threshold value. The thermal does was lower than the CEM43 dose threshold and, therefore, a CTE battery short is not expected to rise above the predefined acceptance value.

Analysis of DC electric field effects on bone tissue

Bench testing was conducted to measure the direct-current electric field effects that the cemented intra-osseous battery may apply to the surrounding bone tissues.

Since there are currently no standards available to support the evaluation of direct-current electric effects of intra-osseous batteries, Clause 16.2 of ISO 14708-7 ("Implants for surgery – Active implantable medical devices – Particular requirements for cochlear implant systems") provides a comparable limit of the maximum allowable direct current level at 100 nA from any of the current pathways. A potential failure pathway that can exposes tissue or fluids to the CTE radio loop antenna is the following concurrent failures; a) failure or fracture of the PEEK nose cone, and b) failure or fracture of the backfill epoxy. Under these simultaneous failures, fluids may come in contact with the CTE loop antenna and provide a conductive pathway to surrounding tissues.

Production-equivalent CTE testers were assembled and modified to provide an additional electrical connection at the point where the DC-blocking capacitor connects to the CTE loop antenna. This is the point of worst-case electrical activation since the other side of the antenna is shorted to GND and the simulated point of conductive liquid contacts with the CTE loop antenna. To evaluate a worst-case condition in addition to the multiple failures of both the PEEK nose cone and epoxy fill, the electrode impedance was modeled at (b) (4) kilo-Ohms. Measurements were performed on a quantity of (b) (4) CTE testers with both the normal operating mode (radio in SLEEP mode) and the radio in active wireless session (RF active) mode. The highest measured simulated tissue current was 33.1 nA, which is well below the safety limit of 100 nA for direct currents established for cochlear implants.

PERFORMANCE TESTING - BENCH

System Integration Validation Testing

System integration testing was performed to validate the intended end-to-end behavior of the CTE with CHIRP system, including access, account creation, and subsystem interaction designed for use in both the home and hospital operating room environments.

To demonstrate that the system can successfully perform the following functions as intended by the end-user:

- Canary admin setup of hospital and hospital admin
- Hospital administrator set up of Doctor

- Doctor registration and set up of patient
- Patient registers and sets up base station
- OR application used for day of surgery to test and activate implant, and link the implant to the patient
- Patient ability to view CMGP parameters on Canary Cloud Patient Dashboard user interface
- Doctor's ability to view patient's CMGP parameters on Canary Cloud Physician Dashboard user interface

Mechanical Bench Testing

CTE Shock Survival

Bench testing was performed to demonstrate that the CTE was designed and constructed to withstand the mechanical shocks caused by mishandling during implant procedure and mechanical forces that may occur during normal conditions of use, including the time prior to implantation. CTEs were exposed to a range of controlled shock and vibration conditions to verify survival of the CTE when exposed to anticipated worst-case conditions. A sample size of (b) (4) production-equivalent CTEs were used. All CTE samples passed all pass/fail criteria, demonstrating normal operation of the CTEs after cumulative exposure to shocks and random vibration.

CTE Transverse Fatigue Testing

Bench testing was performed to provide objective evidence that the CTE has enough fatigue strength to survive worst-case loading conditions without compromising the hermetic integrity of the interior electronics package. Fatigue testing comprises of two sets of cyclic loads. The first set tested CTE implants at (b) (4) Nm, the theoretical 10 million cycle fatigue strength of the comparator Zimmer MG II Construct. The second set introduces an additional series of incrementally higher peak loads in order to compare fatigue life behavior to the reference device (MGII). Testing was performed until the fatigue equipment detected a change of (b) (4) % in the minimum or maximum peak displacement of the device under test or until (b) (4) cycles have completed (whichever comes first). To simulate poor bone support at the tibial plate, testing utilized a point load contact on the CTE implant configured to contact the CTE implant at (b) (4) mm underneath the inferior surface of the tibial plate and at the distal end of the stem extension.

All samples tested at an applied moment of (b) (4) Nm ran out to (b) (4) cycles. Visual inspection under (b) (4) magnification of the samples tested at an applied moment of (b) (4) Nm showed no evidence of a breach in the hermetic enclosure. All CTE implants passed all pass/fail criteria, demonstrating that the CTE has enough fatigue strength to survive worst-case loading conditions without compromising the hermetic integrity of the interior electronics package.

Wear Debris Characterization Testing

Simulated bench testing was conducted to assess the amount of generated wear debris during the service life of the CTE implant. CTE implant samples were placed in test fluid

medium maintained at [redacted] °C. Worst-case fatigue testing was conducted per ASTM F1800 ("Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements") at a peak fatigue load of 900N per ISO 14789 ("Implants for surgery - Total knee-joint prostheses - Part 1: Determination of endurance properties of knee tibial trays"). Testing was performed in a fluid test medium maintained at [redacted] °C. The fluid test medium was extracted, and particulate matter was analyzed utilizing standards ASTM F561-13 ("Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids"), ASTM 1877-16 ("Standard Practice for Characterization of Particles"), and ISO 17853-2011 ("Wear of implant materials – Polymer and metal wear particles - Isolation and characterization"). All specimens reached 10,000,000 cycles of fatigue loading at [redacted] Nm. Optical inspection of the constructs under [redacted] x magnification showed no evidence of fracture, cracking, or deformation. The conclusion of this report is that the CTE implant and a previously cleared comparator Zimmer Biomet stem extension generate similar amounts of particulate matter when cemented and assembled to the Zimmer Biomet Persona tibia tray and loaded per ASTM F1800.

Gravimetric analysis was also performed. The loaded samples showed mass gain higher than the unloaded passive control samples, which is the opposite of the expected results. The potential cause for the discrepancy in mass gain with that expected by ISO 14243-2 ("Implants for surgery – Wear of total knee-joint prosthesis; Part 2 – Methods of measurement")is based on the mechanism described in Measurement Good Practice Guide No. 102, Adsorption and Diffusion of Moisture in Polymeric Materials (ISSN 1368-6550). Duncan and Broughton found that the moisture adsorption rate of epoxy material is influenced by tensile stress. ISO 14243-2allows for either unloaded or loaded soak controls but does not anticipate the tensile loading that would be seen in the cantilever loading scenario used in the wear debris characterization test protocol.

CTE Static Pull Force Test

Bench testing was performed to evaluate the static axial strength of the proximal taper interface of the subject CTE implant and Zimmer Persona Tibial Baseplate in comparison to the Zimmer NexGen knee system. The Canary Tibial Extension is intended for use with the Zimmer Persona tibial base plate, which uses a taper interface as the primary means of locking to the mating component and includes a secondary locking mechanism in the form of a transverse set screw.

The test protocol also was intended to characterize the proximal taper interface of the CTE implant under an applied torsional load. Testing evaluated torque-out characteristics both before and after the application of a cyclic transverse fatigue load. The subject device axial and torsional pull force were higher than the previously cleared Zimmer knee systems and, thus, satisfied the proposed acceptance criteria.

CTE Implant Characterization and Verification Testing

CTE Inertial Motion Unit (IMU) Performance Testing

Bench testing was performed to verify that the subject device meets IMU performance requirements for intended use. The IMU in the CTE contains a three-axis accelerometer and a three-axis gyroscope. The CTE was exposed to a range of controlled acceleration and rotation rate conditions to verify performance of the three-axis accelerometer and three-axis gyroscope, respectively. The testing also verifies the integrated self-test functions, IMU calibration, IMU accelerated life stability, IMU shock and vibration stability and CMGP sensitivity to IMU drift.

For IMU accelerated life stability testing, test results show that the accelerometer and gyroscope offset were within specified limits of the IMU accuracy and reliability, as stated in the manufacturer datasheet. For IMU shock and vibration stability testing, worst-case shock testing was performed on CTE samples, including shocks of both (b) (4) g and (b) (4) g applied load. Test results show all IMU calibration coefficient shifts were well within the ranges determined from accelerated life testing, demonstrating no significant IMU drift that would impact longitudinal activity and gait interpretation. For CMGP sensitivity to IMU draft, the worst-case effects were evaluated using "simulated aged" calibration coefficients. For each simulation, the CTE for each test subject was randomly biased, resulting in (b) (4) unique CTE calibrations with random calibration coefficient shifts to simulate long-term IMU drift. Across the (b) (4) simulations of IMU drift spanning the 6-sigma limits of measured data, only one (1) of the "aged" devices resulted in a reported walking speed shift outside the clinically significant range of +/- (b) (4) m/s, indicating the probability of a clinically significant erroneous walking speed value after 9.1 years is approximately (b) (4) under the assumptions used for this simulation study.

CTE Internal Moisture

Bench testing was performed to verify that the design and assembly procedures of the CTE meet the electronics hermeticity requirement that the CTE internal electronics and battery modules be housed in a hermetically sealed enclosure. The scope of the test is limited to the hermetic assembly comprising the battery and electronics enclosure assembled through the first leak test. Also, the concentration of internal moisture within the hermetic electronics enclosure was captured as an additional indicator of the sealing process quality. The acceptance criterion requires all test samples to have an internal moisture concentration less than 5000 parts per million (ppm). Internal moisture concentrations on the five test samples ranged from (b) (4) to (b) (4) ppm, which meets the proposed acceptance criterion.

CTE Physical Properties

Characterization testing was performed to verify the CTE implant meets mass, surface finish, corrosion resistance, and particulate requirements. Corrosion resistance testing was evaluated according to methods specified in ASTM F2129-15 ("Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices"). The CTE implant was tested to

evaluate particulate matter release are at acceptable levels per clause 14.2 of ISO 14708-1 ("Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer").

CTE Electronic Function

Verification testing was performed to evaluate that the following electronic component requirements were met:

- Radio: The CTE shall have a Radio system capable of exchanging data with Base Stations.
- Non-Volatile Memory: The CTE shall have internal non-volatile memory to store data.
- Inertial Measurement Unit: The CTE shall have an IMU consisting of 3 linear acceleration axes and 3 angular velocity axes.
- Real Time Clock: The CTE shall have an internal RTC that maintains time and provides wake-up inputs to other subsystems.
- Processor: The CTE shall have a processor that manages the functions of the other subsystems.
- Memory Size: The Internal Memory shall have minimum capacity of 16 Mbits.
- IMU Resolution: The IMU linear acceleration and rotational rate data resolution shall be at least 12 bits.

All acceptance criteria were met to demonstrate that design outputs met design inputs.

Bone Loss Cadaver Study

A cadaver study using osteoporotic tibias was performed to demonstrate the amount of bone loss and revision requirements upon removal of a well-cemented subject CTE implant compared to the extraction and revision of a control group using standard primary TKA. Specimens with documented osteopenia/osteoporosis were chosen to simulate a compromised patient population that are at increased risk for fracture during removal. The primary objective of this study was to evaluate the CTE with CHIRP System to ensure that risks associated with the potential for bone loss during the CTE implant removal are acceptable in comparison to extraction and removal of a 510(k)-cleared, standard TKA system with a 30mm stem extension. Surgeon evaluators assessed the clinical acceptability of the CTE with CHIRP System using the risk mitigations employed for acceptable, safe use of the implant.

(b) (4) surgeons performed a total of (b) (4) implantations using the CTE with CHIRP System. There were (b) (4) Persona with 30mm stem tibial constructs with standard cementation, (b) (4) Persona with CTE implant constructs with standard cementation, and (b) (4) Persona tibial constructs with CTE with full cementation. After the primary TKA (tibia only) was performed, the specimen was set for 30 minutes to allow cement to be considered cured and the TKA complete. After this time, the tibia construct of each specimen was removed. After removal, each surgeon visually assessed bone loss and observations were recorded on an Evaluation Questionnaire.

CAD models of the different implant constructs were analyzed to characterize a quantitative volume of bone loss. Evaluation shows a (b) (4)% increase in bone volume removal of the CTE implant attached to the largest Zimmer Biomet Persona tibia plate compared to the largest Zimmer Biomet Person tibia plate and +30 mm Stem (16.4 cm^3 vs. 13 cm^3). Also, the additional bone removal volume was analyzed when considering drill procedure that creates the cavity for the implant constructs' tibial stems. The additional bone removal caused by the respective drills shows about a (b) (4)% increase in bone volume removal of the CTE with CHIRP System Drill with the largest Zimmer Biomet Persona tibia plate compared to the largest Zimmer Biomet Person tibia plate and drill (20.8 cm^3 vs. 15.6 cm^3). While bone loss volume of the CTE with CHIRP System is greater than the Zimmer Biomet Persona with Stem System, the increase in bone loss volume was determined to be clinically acceptable by the surgeon evaluators.

Cadaveric Design Validation Testing

The primary objective of this cadaveric study is to evaluate the CTE with CHIRP System to ensure that the System conforms to the defined intended use and user needs within the surgical environment. Surgeon evaluators determined clinical acceptability of the CTE with CHIRP System and the risk mitigations employed for acceptable and safe use of the implant, surgical instruments, and surgical technique. Surgeon participants answered Design Validation Questionnaires, which required a "Yes" answer fort the System to be found acceptable. The cadaveric study evaluated:

- Use of the CTE X-Ray Template to assess anatomy
- Use of the subject surgical instrumentation (Tibia Cut Guide, Drill, CTE Provisional) to prepare and properly size the anatomy for a CTE Implant with a Zimmer Biomet Persona Personalized Knee System (K113369)
- Use of the subject surgical instrumentation (Impaction Sleeve) to assemble the CTE Implant to the Persona tibia plate component
- Final implantation and the CTE with CHIRP System surgical technique.

For evaluation of the CTE with CHIRP System, each related question in the questionnaire was answered "Yes." For evaluation of drill bit feedback and risk of tibia cortical perforation, all surgeons felt contact with cortical bone. For surgeon evaluation of the CMGP dashboard, all surgeons answered "Yes" for each related question in the questionnaire. For evaluation of wireless quality of service, distance of (b) (4), and (b) (4) meters were used with relative position of the base station to the cadaver knee with CTE implant. 100% of (b) (4) attempts succeeded in connecting to the implant. Only (b) (attempts took over a minute to connect to the implant (97.98% of attempts were under (b) (4) seconds). Moreover, (b) (4) connection attempts at (b) (4) meters were successful while the subject device product requirement is only 2 meters.

For CMGP validation, each of (b) (4) specimen knees, (b) (4) data captures were completed for a total of (b) (4) datasets. The CMGP algorithm identified 6 to 8 qualified gait cycles for a total number of 120 gait cycles. The CMGP results for each of the (b) (4) data sets is shown below:

Table 5: CMGP results from prone cadaver knee maneuvers from full extension to 90-degree flexion

Specimen	L/R	Trial #	Cadence (steps/min)	Stride Length (m)	Walking Speed (m/s)	Tibia ROM (deg)	Knee ROM (deg)
(b) (4)							
Average:	(b) (4)						
Standard Deviation:							
Maximum:							
Minimum:							

Based on the experimental design with no net motion and the details of the CMGP algorithm, walking cadence and tibia range of motion are most likely to reflect actual motion of the cadaver knee joints. The CMGP calculated average cadence was (b) (4) steps/minute and average tibia range of motion was (b) (4) degrees. Other CMGP metrics including stride length, walking speed, and functional knee range of motion were similar to results for normal walking reported in the Gait Parameters Design Validation testing.

The test results demonstrated successful data collection, wireless data transmission, and data processing from the CMGP algorithm. The testing also demonstrated that surgeons are able to follow directions of the surgical technique and comprehend displayed data on the CMGP Dashboard.

Gait Parameters Design Validation

The test objective was to validate the performance of the CTE with CHIRP System by measuring the Canary Medical Gait Parameters (CMGP) mean percent error (MPE) in comparison to an established and accepted gold standard kinematic gait measurement system. The primary endpoint was to demonstrate the walking speed reported by the CTE with CHIRP System is equivalent to the walking speed measured by a gold standard

system. Secondary endpoints were to report accuracy of the remaining CMGP – Cadence, Stride Length, Functional Knee Range of Motion (ROM), and Tibia Range of Motion – compared to the gold standard system.

A total of (b) (4) test subjects were recruited. Test subjects wore an (b) (4) Simultaneously, kinematic data were collected by the CTE implant and the motion capture system for comparison. The range of test speeds covered both acute (2-weeks post-surgery) and long term (12-months post-surgery) recovery phases.

Based on literature findings[1], the reported minimal clinically important improvement in walking speed was 0.32 m/s; therefore, this value was utilized as the pre-specified threshold indicative of the minimal clinically important change in walking speed for patients who have undergone TKA. Instead of pre-defining a statistical hypothesis for test comparison of these parameters to the motion capture system, the mean percentage error (MPE) was calculated across all steps and all subjects at each walking speed and Bland-Altman analyses comparing these measures to the camera-based motion capture system was performed and reported.

Step count was measured directly by the CTE's internal IMU using the standard Android 4.4 step counting function and was not evaluated in this protocol. The Distance CMGP parameter was derived by multiplying Step Count by Stride Length and was also not evaluated as a part of this protocol.

Test results show that walking speed were within pre-specified equivalence bounds of 0.32 m/s. Since the CTE measure of walking speed is considered equivalent to camera-based motion capture, the primary endpoint was met. The 95% confidence limits for the mean were all below zero, indicating that the CTE consistently underestimated walking speed, but results for each speed were also within the equivalence bounds for the primary analysis, indicating any difference has minimal clinical importance.

Table 6: Walking speed mean, standard deviation, and 95% confidence limits of error across walking speed

Treadmill Speed	Mean Error (m/s)	Standard Deviation (m/s)	95% Confidence Limits (m/s)
(b) (4)			

[1] K. C. Foucher, "Identifying clinically meaningful benchmarks for gait improvement after total hip arthroplasty," J. Orthop. Res., vol. 34, no. 1, pp. 88–96, Jan. 2016.

Of the secondary endpoints, the most accurate CTE measurement across all walking speeds was cadence while stride length was the least accurate. The 95% confidence limits for stride length and tibia range of motion do not include zero, indicating that the CTE with CHIRP consistently underestimated these values. In comparison to the use of plastic goniometers, the knee range of motion measurements of the CTE implant are more accurate. Due to the limitations of the test setup (e.g., soft tissue movement, the implant not being rigidly attached to the tibia with bone cement, unwanted CTE micro motion, misalignment), the test environment represents a worst-case test scenario.

Table 7: Secondary Endpoint CMGP Mean Values and Mean Error as a function of treadmill walking speed for all subjects

PARAMETER	UNITS	TREADMILL WALKING SPEED
		(b) (4)
Cadence	step/min	
Stride Length	m	
Functional Knee ROM	deg	
Tibial ROM	deg	

Usability Testing

Human factor usability (HF/U) validation testing was performed for the use of the CTE with CHIRP System with (b) (4) groups of study participants identified as circulating nurses in the operating room (OR) environment, patients in the home environment, and surgeons. Protocol designs for HF/U validation testing were consistent with the FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices."

A home environment formative usability test was performed to evaluate the home base station, the patient portal, and supporting user documentation. A total of (b) (4) lay users from the general population was recruited to participate in a usability validation study of the CTE with CHIRP System with the patient user group in the home environment. Participants completed simulated-use tasks and answered critical knowledge questions in order to evaluate the usability of the CTE with CHIRP System for the home environment. The results of the home usability testing did not reveal any significant end-user problems with device.

An OR environment formative usability test was performed to evaluate the surgical technique and Physician Instructions for Use labeling and the use of CTE with CHIRP system components in an OR environment. Design strengths and opportunities for improvement were identified with the aim of improving the overall usability of the system through mitigating any observed use error.

All results and design recommendations were reviewed, and design modifications were implemented in response to key findings during usability activities.

Human factors testing also included surgeon evaluation, which was described in the Cadaveric Design Validation Testing subsection above.

LABELING

The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System labeling consists of the following: device description, indications for use, instructions for use, contraindications, warnings, and precautions, MR compatibility, shelf life, potential adverse events, and disposal instructions. The labeling meets the requirements of 21 CFR 801.109 for prescription devices and specifically indicates that the device is not intended to be utilized for clinical decision-making and no data have been evaluated to support the demonstration of clinical benefit. Furthermore, the sterile packaging includes a shelf life for the device, and the labeling includes reprocessing instructions for the reusable instruments.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of an implantable post-surgical kinematic measurement knee device:

Identified Risks to Health	Mitigation Measures
Tissue injury, thermal injury, or electric shock due to device failure including: • Loss of hermeticity • Battery failure	Thermal safety testing Electrical safety testing Battery safety testing Non-clinical performance testing
Loosening/migration due to device failure at the bone/implant interface	Non-clinical performance testing Labeling
Inaccurate, unreliable, and irreproducible kinematic data leading to improper post-surgical patient management	Non-clinical performance testing
Interference with imaging modalities	Non-clinical performance testing Magnetic resonance compatibility testing
Data access failure and delayed access to kinematic data due to: • Software failure • Interference with other devices • Use error	Software verification, validation, and hazard analysis Electromagnetic compatibility (EMC) testing Human factors testing Labeling
Infection	Sterilization validation Reprocessing validation Biocompatibility evaluation

Identified Risks to Health	Mitigation Measures
	Labeling
Adverse tissue reaction	Biocompatibility evaluation

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the implantable post-surgical kinematic measurement knee device is subject to the following special controls:

1. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following tests must be conducted:
   a. Mechanical testing must evaluate the mechanical function (mechanical fatigue, static mechanical strength) and durability of the implant;
   b. Simulated use testing must evaluate the ability of the device to be sized, inserted and sufficiently secured to any compatible components;
   c. Testing must demonstrate the accuracy, reliability, and reproducibility of kinematic measurements; and
   d. Testing must demonstrate diagnostic and therapeutic ultrasound conditions for safe use.
   e. Testing must demonstrate that the device performs as intended under anticipated conditions of use demonstrating the following performance characteristics, if applicable:
      i. Magnetic pulse output testing
      ii. Magnetic and electrical field testing
      iii. Testing of the safety features built into the device.
   f. Testing must demonstrate hermeticity of any electronic component enclosures.
2. Performance testing must evaluate the compatibility of the device in a magnetic resonance (MR) environment.
3. Human factors testing must demonstrate that the intended user(s) can correctly use the device for its intended use, including for implantation and post-procedure data access.
4. Performance data must demonstrate the sterility of the device implant and patient-contacting components.
5. Performance data must validate the reprocessing instructions for the reusable components of the device.
6. The patient-contacting components of the device must be demonstrated to be biocompatible.
7. Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.
8. Performance testing must demonstrate the electromagnetic compatibility/interference (EMC/EMI), electrical safety, thermal safety, battery safety, and wireless performance of the device.
9. Software verification, validation, and hazard analysis must be performed.
10. The labeling must include the following:
    a. A shelf life;

b. Physician and patient instructions for use, including images that demonstrate how to interact with the device;
c. Detailed instruction of the surgical technique;
d. Hardware and software requirements for interacting with the device;
e. A clear description of the technological features of the device including identification of the device materials, compatible components, and the principles of operation;
f. Identification of magnetic resonance (MR) compatibility status;
g. Validated methods and instructions for reprocessing of any reusable components; and
h. A statement regarding the limitations of the clinical significance of the kinematic data.

BENEFIT-RISK DETERMINATION

The probable benefits of the device are based on nonclinical laboratory studies as described above.

-The device reliably and reproducibly acquires and outputs kinematic gait measurement data.

-The device provides additional stabilization of the tibial tray component of a total knee arthroplasty construct by virtue of the extended tibial stem length that is provided by the device.

The risks of the device are also based on nonclinical laboratory studies described above.

The major risks associated with this device are:

-Infection
Because of the need for increased duration of surgery required in the operating room to register electronic communication between the stem transmitter and the base station a small increased risk of infection is acknowledged by the sponsor and felt to be acceptable.

-Bone loss and associated loosening of the implant
The incidence of bone loss/loosening in primary TKA is reported as 1-2%. These events usually occur in the longer time frame. These events are known to occur with longer stems and the use of cement. However, risks due to bone loss incurred in either the original surgical procedure, or in any necessary subsequent revision, should be no greater than those for a cemented and comparably sized (58mm) tibial stem extension device.

-Abnormal bony response to the novel construct of titanium, PEEK, and PMMA bone cement.

-If the intraosseous battery of this device has not been removed from a deceased patient prior to cremation, there is a risk of damage to crematory facilities and injuries to personnel from explosion of the battery when subjected to cremation temperatures.

-Deleterious long-term effects due to the generation of wear debris, inflammatory responses, etc. emanating from the various titanium/PEEK/PMMA bone cement components and component interfaces. Wear testing and wear debris characterization were utilized by the sponsor to mitigate this risk.

PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

> The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System is intended to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.
>
> The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58mm sized tibial stem extension.
>
> The objective kinematic data generated by the CTE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.
>
> The CTE with CHIRP System is compatible with Zimmer Persona® Personalized Knee System.

The probable benefits outweigh the probable risks for the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo for the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System is granted, and the device is classified as follows:

Product Code: QPP

Device Type: Implantable post-surgical kinematic measurement knee device

Regulation Number: 21 CFR 888.3600

Class: II