



August 27, 2021

Canary Medical, Inc.
Nora York
Senior Director, Regulatory Affairs and Quality Assurance
2150 Western Parkway, Suite 202
Vancouver, British Columbia V6T 1V6
Canada

Re: DEN200064

Trade/Device Name: Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System

Regulation Number: 21 CFR 888.3600

Regulation Name: Implantable post-surgical kinematic measurement knee device

Regulatory Class: Class II

Product Code: QPP

Dated: October 15, 2020

Received: October 19, 2020

Dear Nora York:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System, a prescription device under 21 CFR Part 801.109 with the following 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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System, and substantially equivalent devices of this generic type, into Class II under the generic name Implantable post-surgical kinematic measurement knee device.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On October 19, 2020, FDA received your De Novo requesting classification of the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are tissue injury, thermal injury, electric shock, loosening, migration, inaccurate/unreliable/irreproducible kinematic data, interference with imaging modalities, data access failures and delayed access to kinematic data, infection, or adverse tissue reaction. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Tissue injury, thermal injury, or electric shock due to device failure including: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Software failure • Interference with other devices • Use error 	Software verification, validation, and hazard analysis Electromagnetic compatibility testing Human factors testing Labeling
Infection	Sterilization validation Reprocessing validation Biocompatibility evaluation Labeling
Adverse tissue reaction	Biocompatibility evaluation

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Implantable post-surgical kinematic measurement knee device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for

combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Patrick Macatangga at 301-796-4369.

Sincerely,

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health