March 24, 2023

Canary Medical USA LLC
Kevin Leung
Associate Director, Regulatory Affairs
2710 Loker Ave. West, Suite 350
Carlsbad, California 92010

Re: K223803
Trade/Device Name: Canary Tibial Extension (CTE) 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: February 24, 2023
Received: February 27, 2023

Dear Kevin Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Ting Song -S

Ting Song, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223803/S001

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

Indications for Use *(Describe)*
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 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Sponsor:	Canary Medical USA LLC 2710 Loker Ave. West, Suite 350 Carlsbad, CA 92010
Establishment Registration Number:	3015802419
Contact Person:	Kevin Leung Associate Director, Regulatory Affairs Mobile: 562-547-4067 Email: kleung@canarymedical.com
Subject Device:	Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System
Regulation Number:	21 CFR 888.3600
Product Code:	QPP
Device Class:	II
Predicate Device:	Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System (DEN200064)
Device Description:	The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System is comprised of the following subsystems: • Canary Tibial Extension (CTE) implant, • Operating Room (OR) Base Station System ("BS1"), • Home Base Station System ("BS2"), • Canary Cloud Data Management Platform ("Cloud") and • Canary Medical Gait Parameters (CMGP software module). The CTE and CHIRP System is intended to provide objective kinematic data on patient's total knee arthroplasty (TKA) function. The kinematic data produced by the CTE implant is intended as an adjunct to other physiological measurement tools post TKA surgical care while providing additional tibial stability afforded by traditional tibial extensions of similar length. The implanted CTE collects data from internal motion sensors, and when queried by a BS1 or BS2 over a communication interface, transmits the motion data to the Base Station System. The Base Station System, in turn, uploads the data to the Canary Cloud Data Management Platform. The User is defined as the Patient with the CTE and CHIRP System and their designated Health Care Professional (HCP) with access to the Patient's CTE data.

	The CTE is designed for use with the Zimmer Biomet Persona Personalized Knee System tibial baseplate, to provide additional stability and collect kinematic data to assist the physician in monitoring patient activity following total knee arthroplasty (TKA) in between office visits. The Canary Quantiles Recovery Curves software is an accessory and an optional software module for use with the CTE with CHIRP System. The software obtains kinematic data from the CTE with CHIRP System and provides aggregation and visualization of patient population data to HCPs to analyze patient recovery progress and direction of outcome.
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.
Summary of Technological Characteristics and Comparison:	The rationale for substantial equivalence is based on comparative assessment of the following characteristics: • **Indications for use**: Same as the predicate device. • **Intended Use**: Same as the predicate device. • **Materials**: Same as the predicate device. • **Design Specifications (hardware)** Same as the predicate device. • **Performance**: Same as predicate device. • **Sterility**: Same as the predicate device. • **Packaging**: Same as the predicate device.
Summary of Performance Data:	The following non-clinical activities were performed to support the modifications to the subject device: • Software Verification & validation • System Integration Validation
Substantial Equivalence	The subject device has the same intended use and technological

Conclusion:	characteristics to the predicate, and the performance data and analyses demonstrate that: • any differences do not raise new questions of safety and effectiveness; and • the proposed device is at least as safe and effective as the legally marketed predicate device.