April 24, 2024

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

Re: K234056
Trade/Device Name: canturio® se (Canturio Smart Extension)
Regulation Number: 21 CFR 888.3600
Regulation Name: Implantable Post-Surgical Kinematic Measurement Knee Device
Regulatory Class: Class II
Product Code: QPP
Dated: March 25, 2024
Received: March 25, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.04.24 01:21:50 -04'00'

For Lixin Liu, 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.

Submission Number *(if known)*

K234056

Device Name

canturio® se (Canturio Smart Extension)

Indications for Use *(Describe)*

The canturio® se (Canturio Smart Extension) 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 30mm sized tibial stem extension.

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

The canturio® se 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	canturio® *se* (Canturio Smart Extension) (K234056)
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)
Purpose of Submission:	The purpose of this submission is to seek 510(k) clearance for the canturio® *se* (Canturio Smart Extension or CSE) implant designed to replicate the canturio® *te* (Canturio Tibial Extension or CTE) (**predicate device**; reference DEN200064) as a product line extension offering of smaller size for patients whose physician believe would benefit from a 30mm-sized tibial stem and adjunctive kinematic gait data, remote monitoring, post-total knee arthroplasty (TKA) surgery.
Device Description:	The canturio® *se* is a tibial extension implant or stem that is attached by the orthopedic surgeon to the Zimmer Biomet Persona® tibial baseplate to form the patient's tibial knee prosthesis. The software and electronics embedded within the canturio® *se* prosthesis collect the patient's functional movement and gait parameter data post-surgery. Like a traditional tibial extension, the canturio® *se* provides additional stability in the same manner as a traditional knee extension. The canturio® *se* (Canturio Smart Extension or CSE) is used with the Canary Health Implanted Reporting Processor (CHIRP) System which is comprised of the following subsystems: • Operating Room Base Station Subsystem ("OR BS"),

	• Home Base Station Subsystem ("HBS"), • Canary Cloud Data Management Platform ("Cloud" or "CMDP") subsystem and • Canary Medical Gait Parameters (CMGP) software module. Each CHIRP subsystem combines physical components, electronics, software, and user interfaces to collect, store, analyze, transmit, and display patient data for use by both physicians and patients.
Indications for Use:	The canturio® *se* (Canturio Smart Extension) 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 30 mm sized tibial stem extension. The objective kinematic data generated by the canturio® se with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit. The canturio® *se* with CHIRP System is compatible with Zimmer Biomet Persona® The Personalized Knee® System.
Summary of Technological Characteristics and Comparison:	The rationale for substantial equivalence is based on comparative assessment of the following characteristics: • **Intended use:** Same as the predicate. • **Indications for use**: Substantially equivalent to the predicate with the only difference in shorter length variant. • **Materials**: Same as the predicate device. • **Geometry/Configuration/Size (of Tibial Extension)**: Same geometry/configuration as the predicate device but shorter length.

	• **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 tests were performed to support the modifications to the subject device: • Mechanical Fatigue • Shock Survival • Electrical Life Test • Accuracy, reliability, and reproducibility of kinematic measurements • Electromagnetic compatibility (EMC) and electromagnetic interference (EMI) • Hermeticity of any electronic component enclosures • Biological Evaluation • Battery Longevity • Electronic Functionality • Software Verification • Magnetic Resonance Compatibility
Substantial Equivalence Conclusion:	The subject device has the same intended use and substantially equivalent indications for use as the predicate device. The subject device has the same technological 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.