June 27, 2023

Enztec Limited
℅ Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K230876
Trade/Device Name: RI.KNEE Adjustable Tibia Cut Guide
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 30, 2023
Received: March 30, 2023

Dear Nathan Wright:

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,

Tejen D. Soni -S
2023.06.27
16:39:00 -04'00'

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and
and Trauma 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)*
K230876

Device Name
RI.KNEE Adjustable Tibia Cut Guide

Indications for Use *(Describe)*
The RI.KNEE Adjustable Tibia Cut Guide is intended to be used in conjunction with the CORI surgical system during total knee arthroplasty.

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

Submitter's Name:	Enztec Limited
Submitter's Address:	3/17 Print Place Middleton, Christchurch 8024
Submitter's Telephone:	+64 27 829 2440
Contact Person:	Nathan Wright MS Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	March 30, 2023
Trade or Proprietary Name:	RI.KNEE Adjustable Tibia Cut Guide
Device Classification Name:	Orthopedic Stereotaxic Instrument
Classification & Regulation #:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Stereotaxic, Trauma and Restorative Devices (DHT6C)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The subject RI.KNEE Adjustable Tibia Cut Guide is a set of surgical instrument components used during total knee arthroplasty (TKA) to make the resections to the tibia by guiding a surgical saw through the saw slot. The cut guide is used with the Smith and Nephew (Blue Belt Technologies) CORI surgical system. The subject Tibia Cut Guide offers an alternative to the tibia cut guides currently available in the CORI system and provides direct attachment of the tibia tracker to reduce surgical steps for tibia tracker fixation.

INDICATIONS FOR USE

The RI.KNEE Adjustable Tibia Cut Guide is intended to be used in conjunction with the CORI surgical system during total knee arthroplasty.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have similar technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are comparable between the subject and predicates:

- Indications for Use
- Materials of manufacture
- CORI Surgical System Application
- Function – Knee Resection

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K221224	Real Intelligence Cori (Cori)	Blue Belt Technologies, Inc.	OLO	Primary

PERFORMANCE DATA

The RI.KNEE Adjustable Tibia Cut Guide has been tested in the following test modes:

- Summative Usability Evaluation
- Function and Robustness Testing

In addition to the bench testing, the instrument biocompatibility and the instrument cleaning and sterilization processes have been evaluated. The results of this non-clinical testing and evaluations show that the performance of the RI.KNEE Adjustable Cut Guide is sufficient for its function and intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the RI.KNEE Adjustable Cut Guide is substantially equivalent to the predicate device.