Tornier Inc.
Renee Stoffel
Principal Regulatory Affairs Specialist
10801 Nesbitt Ave South
Bloomington, Minnesota 55347

August 5, 2020

Re: K193247
Trade/Device Name: LATITUDE EV™ Total Elbow Arthroplasty system
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDB, JDC
Dated: July 8, 2020
Received: July 10, 2020

Dear Renee Stoffel:

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,

For Michael Owens
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193247

Device Name
LATITUDE EV™ Total Elbow Arthroplasty

Indications for Use *(Describe)*

The LATITUDE EV™ Total Elbow Arthroplasty system is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.

The LATITUDE EV™ Total Elbow Arthroplasty system is intended for cemented use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Date Prepared: July 8, 2020

Administrative Information

Name:	Tornier, Inc.
Address:	10801 Nesbitt Avenue South Bloomington, MN 55437 United States of America
Contact Person:	Renee Stoffel
Title:	Principal Regulatory Affairs Specialist
Phone:	952-683-7471
Fax:	952-426-7601

Device Information

Name of Device:	LATITUDE EV™ Total Elbow Arthroplasty
Common Name (s):	Elbow Prosthesis
Regulatory Class:	II
Regulation:	21 CFR 888.3160, elbow joint metal/polymer semi-constrained cemented prosthesis. 21 CFR 888.3150, elbow joint metal/polymer constrained cemented prosthesis.
Product Codes:	JDB JDC

Predicate Device Information

Primary Predicate:	K182461, LATITUDE EV™ Total Elbow Arthroplasty
Additional Predicate:	K171010, LATITUDE EV™ Total Elbow Arthroplasty
Reference Devices:	K070787, LATITUDE™ Elbow Prosthesis K053189, COONRAD/MORREY TOTAL ELBOW, MODEL 8105 SERIES

Device Description

The LATITUDE EV™ Total Elbow Arthroplasty system is a total elbow prosthesis consisting of a humeral, an ulnar, and an optional radial implant. The LATITUDE EV system is designed to facilitate the reproduction of the natural flexion/extension axis and kinematics of the elbow. The prosthesis is a semi-constrained prosthesis when it is implanted in an unlinked configuration and becomes a constrained prosthesis when the ulnar cap is used to link the humeral and ulnar implant assemblies. All components are intended for cemented use only.

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Indications for Use

The LATITUDE EV™ Total Elbow Arthroplasty system is intended for total elbow arthroplasty. Prosthetic replacement with this device may be indicated to relieve severe pain or significant disability following the effects of primary or secondary osteoarthritis and rheumatoid arthritis; correction of functional deformities; revision procedures where other treatments or devices have failed; treatment of fractures that are unmanageable using other techniques.

The LATITUDE EV™ Total Elbow Arthroplasty system is intended for cemented use only.

Comparison to Predicate Device

The initial manufacturing process for the LATITUDE EV humeral and ulnar stems was changed from forging to casting for a subset of the stem sizes and lengths. Additional modifications for the subject components include sterile packaging materials, labeled shelf life, dimensional specifications, and material specifications. These manufacturing and design differences do not raise new issues of safety or effectiveness and are supported by performance testing and process validations.

Non-clinical Performance Testing

Non-clinical testing was performed to demonstrate substantial equivalence to the predicate device.

- Humeral and ulnar stem fatigue testing
- Plasma-sprayed coating characterization and testing to ASTM F1854-15, ASTM F1160-14, ASTM F1044-05, ASTM F1147-05, ASTM F1978-17
- Biocompatibility evaluation to ISO 10993-1:2018
- Packaging and shelf life evaluations to ISO 11607-1:2019, ISO 11607-2:2019, ASTM F1980-16
- Distribution testing to ISTA Procedure 3A (2011), ASTM D4169-16, ASTM F2096-11
- Sterilization evaluation to ISO 11137-1:2006 and ISO 11137-2:2006
- Endotoxin testing to AAMI ST72:2011

Clinical Testing

No clinical studies were performed.

Conclusions

The LATITUDE EV™ Total Elbow Arthroplasty system does not raise new questions of safety or effectiveness. Differences in technological characteristics have been addressed with performance testing. The results of performance testing for the modified LATITUDE EV™ humeral and ulnar components support substantial equivalence to the current LATITUDE EV™ system (K182461).