



Tornier Inc.
Renee Stoffel
Sr. Regulatory Affairs Specialist
10801 Nesbitt Ave South
Bloomington, Minnesota 55437

December 27, 2018

Re: K182461

Trade/Device Name: LATITUDE EV Total Elbow Arthroplasty
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: December 18, 2018
Received: December 20, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa
Vuniqui -S
Digitally signed
by Vesa Vuniqui -S
Date: 2018.12.27
15:19:29 -05'00'

For: Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K182461

Device Name

LATITUDE EV™

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.

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Date Prepared: December 18, 2018

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

Predicate: LATITUDE EV™ Total Elbow Arthroplasty (LATITUDE™ Elbow Prosthesis)
510(k) Number: K100562, K171010
Reference Device: RHS
510(k) Number: K060438

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.

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 of Technological Characteristics with the Predicate Device

Modified radial head and radial stem components will be offered in additional sizes for primary and revision surgery. The new radial stems feature a TI plasma-sprayed coating and the radial head-stem locking mechanism was modified. The new radial components are compatible with existing ulnar and humeral components. The 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 bench testing and process validations were performed to demonstrate substantial equivalence to the predicate device.

- Radial stem fatigue and pull-out testing
- Radial assembly disassociation testing
- Radial head poly bearing analysis
- Plasma-sprayed coating characterization and testing to ASTM F1854-15, ASTM F1160-14, ASTM F1044-05, ASTM F1147-05, ASTM F1978-17
- CT analysis of radial canals
- Tolerance analysis and cadaver lab
- Biocompatibility evaluations to ISO 10993-1:2009
- Cleaning evaluations to ISO 11737-1:2006, AAMI ST72:2011, ISO 10993-5:2009, and ASTM F750-87 for implants and AAMI TIR30:2011 for instruments
- Endotoxin testing to AAMI ST72:2011
- Packaging and distribution evaluations to ISO 11607-1:2006, ISO 11607-2:2006, ISTA Procedure 2A (2011), ASTM D4332-14, ASTM D4169-16, ASTM F2096-11
- Sterilization evaluations to ISO 11137-1:2006 and ISO 11137-2:2006 for implants and ISO 17665-1:2006 for instruments

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™ radial components support substantial equivalence to the current LATITUDE EV™ system (K100562, K171010).