DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 31, 2017

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

Re: K171010
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: August 2, 2017
Received: August 3, 2017

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Katherine D. Kavlock -S

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

Indications for Use

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

510(k) Number *(if known)*
K171010

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.

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510(k) Summary

Date Prepared: April 3, 2017

I. Administrative Information

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

II. Device Information

Name of Device:	Latitude EV™ Total Elbow Arthroplasty
Common Name:	Elbow Prosthesis
Classification Name:	21 CFR 888.3160, elbow joint metal/polymer semi-constrained cemented prosthesis. 21 CFR 888.3150, elbow joint metal/polymer constrained cemented prosthesis.
Regulatory Class:	Class II
Product Code:	JDB JDC

III. Predicate Device Information

Primary Predicate:	Latitude™ Elbow Prosthesis, K100562
Additional Predicate:	Coonrad/Morrey Total Elbow, K053189

IV. Device Description

The Latitude EV™ Total Elbow Arthroplasty system is a 2- or 3-part 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.

The Latitude EV™ humeral and ulnar stems are available in multiple sizes for primary and revision surgery and include a plasma spray coating. The optional radial implant is uncoated and is available in several sizes corresponding to the humeral and ulnar construct size selected.

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V. 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.

VI. Comparison of Technological Characteristics with the Predicate Devices

The Latitude EV™ Total Elbow Arthroplasty system has the same intended use as the predicate devices. The humeral, ulnar, and optional radial implants are identical to those currently marketed in the Latitude EV™ Total Elbow Arthroplasty system (cleared as the Latitude™ Elbow Prosthesis, K100562). The purpose of this submission is to allow implantation of the Latitude EV prosthesis as a 2-part system consisting only of the humeral and ulnar implants. The radial implant will become optional. The two-part configuration is similar in function and design to the Coonrad/Morrey Total Elbow, K053189. The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

VII. Performance Data

Non-clinical performance bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate device.

- Humeral and Ulnar Stem Fatigue Testing
- Ulnar Cap Modular Connection Static Disassociation Testing
- Endotoxin (<20 EU/device)

VIII. Clinical Study

Clinical studies were not required to demonstrate substantial equivalence between the subject device and the predicate device.

IX. Conclusions

The Latitude EV™ system described in this section has the same intended use and the same fundamental scientific technology as the predicate devices. The testing presented for the technological differences between the subject and predicate devices demonstrate that the Latitude EV™ Total Elbow Arthroplasty system is substantially equivalent to the predicate devices.