July 17, 2019

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

Re: K191711
Trade/Device Name: ORTHOLOC™ SPS Shoulder Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, KTW, KTT
Dated: June 24, 2019
Received: June 26, 2019

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191711

Device Name
ORTHOLOC™ SPS Shoulder Plating System

Indications for Use *(Describe)*
The ORTHOLOC™ SPS is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

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: June 24, 2019

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:	ORTHOLOC™ SPS Shoulder Plating System
Common Name(s):	Humeral Plating System
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class:	II
Regulation Number:	21 CFR 888.3030
Product Codes:	HRS, HWC, KTT, KTW

Predicate Device Information

Predicate:	ORTHOLOC™ SPS Shoulder Plating System
510(k) Number:	K181587

Device Description

The ORTHOLOC™ SPS Shoulder Plating System is designed to provide anatomical reduction and stable primary fixation of the proximal humerus using implanted plates and screws. The plates are available in three designs: Standard, Posterior, and Greater Tuberosity (GT) and are manufactured from stainless steel per ASTM F138. The system also includes locking screws manufactured from stainless steel per ASTM F2229 and non-locking screws manufactured from stainless steel per ASTM F138 or ASTM F2229. The system is provided non-sterile and requires steam sterilization prior to use.

Indications for Use

The ORTHOLOC™ SPS is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

Comparison of Technological Characteristics with the Predicate Device

The modifications to the predicate system include the addition of blunt-tipped locking screws and an alternative stainless-steel alloy (ASTM F2229) for cortical non-locking screws.

Non-clinical Performance Testing

To demonstrate substantial equivalence to the predicate device, the following non-clinical bench testing was performed as indicated by risk analysis:

- Screw Torsion, Driving Torque, and Axial Pullout to ASTM F543-17

The subject device passed all testing with the same acceptance criteria as the predicate device.

Clinical Testing

No clinical studies were performed.

Conclusions

The subject device is identical to the predicate device with respect to intended use, principle of operation, and conditions for use. The ORTHOLOC™ SPS Shoulder Plating System does not raise new questions of safety or effectiveness. Differences in technological characteristics that pose potential risks, as identified by risk analysis, have been addressed with verification testing. The results of testing for the modified ORTHOLOC™ SPS Shoulder Plating System support substantial equivalence to the predicate ORTHOLOC™ SPS Shoulder Plating System (K181587).