August 22, 2019

Zimmer GmbH
Danielle Madureira
Senior Specialist, Regulatory Affairs
Sulzerallee 8
Winterthur, 8404 CH

Re: K192021
Trade/Device Name: NCB Polyaxial Locking Plate 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
Dated: July 25, 2019
Received: July 29, 2019

Dear Danielle Madureira:

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)*
K192021

Device Name
NCB® Polyaxial Locking Plate System, Proximal Humerus

Indications for Use *(Describe)*
The NCB Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones.

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

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Danielle Jannuzzi Madureira Senior Specialist, Regulatory Affairs Telephone: +41 58 854 82 60 Fax: + 41 52 244 86 58
Date:	July 25, 2019
Trade Name:	NCB® Plating System, Proximal Humerus
Classification Product Code :	HRS, HWC
Device Classification Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Regulation Number / Description:	21 CFR § 888.3030 – Single/multiple component metallic bone fixation appliances and accessories 21 CFR § 888.3040 – Smooth or threaded metallic bone fixation fastener.
Predicate Device:	NCB® Plating System, manufactured by Zimmer GmbH, K042695, cleared October 29, 2004 NCB® Plating System, Proximal Humerus, manufactured by Zimmer GmbH, K081759, cleared October 16, 2008
Device Description:	The NCB Polyaxial Locking Plate System is an extramedullary internal fixation plate system to be used for proximal humeral fractures. It is intended to be implanted either percutaneously or by a traditional open method. The *Tivanium* 3.5 mm locking screws are used to engage the proximal locking screw holes within the NCB Polyaxial Locking Plate System, Proximal Humeral Plates.

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510(K) SUMMARY

Intended Use:

The NCB Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of fractures and osteotomies of long bones.

Comparison to Predicate Device:

The intended use of the modified devices, as described in its labeling, has not changed as a result of the modifications proposed in the present submission. The line extension does not alter the fundamental scientific technology shared by both the subject devices and predicate devices. The proposed packaging configuration and the methods to support the package integrity have been previously cleared for Zimmer GmbH products. Zimmer GmbH is furthermore seeking clearance for certain system-specific Class II instruments - these instruments that have previously considered Class I exempt and correction of classification to Class II is proposed within present submission.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Class II: Amendment of Design Controls with verification of mechanical integrity and resistance.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

Conclusion:

The subject devices have the same intended use and similar indications for use as the predicate devices. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate devices.

Except for the modifications described in this submission the subject devices are identical to the predicate devices, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness as established with performance testing; and
- the subject devices are at least as safe and effective as the legally marketed predicate devices.