August 15, 2024

Zimmer Switzerland Manufacturing GmbH
Melanie Mitrov
Regulatory Affairs Sr Specialist
Sulzerallee 8
Winterthur, ZH 8404
Switzerland

Re: K241754
Trade/Device Name: NCB® Polyaxial Locking Plate System; NCB® Periprosthetic Femur Plate System; NCB® Cable Button; NCB® Straight Narrow Shaft Plate
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: June 14, 2024
Received: June 18, 2024

Dear Melanie Mitrov:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira -S

Christopher Ferreira, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241754

Device Name

NCB® Polyaxial Locking Plate System;
NCB® Periprosthetic Femur Plate System;
NCB® Cable Button;
NCB® Straight Narrow Shaft Plate

Indications for Use *(Describe)*

NCB® Polyaxial Locking Plate System:
The NCB Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of distal femoral (NCB DF), proximal humeral (NCB PH), and proximal tibial (NCB PT) fractures and osteotomies.

NCB® Periprosthetic Femur Plate System:
The NCB Periprosthetic Femur Plate System is indicated for temporary internal fixation and stabilization of femoral fractures and osteotomies, including periprosthetic fractures.

If combined with the NCB Periprosthetic Trochanter Plate and Connection Screw, the NCB Periprosthetic Proximal Femur Plate is additionally indicated for temporary internal fixation and stabilization of greater trochanter fractures and osteotomies including re-attachment of the greater trochanter following fracture and osteotomy in total hip arthroplasty.

The NCB Periprosthetic Trochanter Plate and Connection Screw can only be used in combination with the NCB Periprosthetic Proximal Femur Plate.

NCB® Cable Button:
The NCB Cable Button for the NCB Polyaxial Locking Plate System in combination with the Zimmer Biomet NCB Polyaxial Locking Plate System and Cable-Ready System Cerclage Cables is indicated for temporary internal fixation of fractures and osteotomies.

NCB® Straight Narrow Shaft Plate
The NCB Straight Narrow Shaft Plate is indicated for temporary internal fixation and stabilization of humeral and tibial shaft fractures and osteotomies, including periprosthetic fractures.

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

Prepared on: 2024-06-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Switzerland Manufacturing GmbH
Applicant Address	Sulzerallee 8 Winterthur ZH 8404 Switzerland
Applicant Contact Telephone	+41791530853
Applicant Contact	Mrs. Melanie Mitrov
Applicant Contact Email	melanie.mitrov@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NCB® Polyaxial Locking Plate System; NCB® Periprosthetic Femur Plate System; NCB® Cable Button ; NCB® Straight Narrow Shaft Plate
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192217	NCB Plating System Distal Femur and Proximal Tibia	HRS
K192021	NCB Polyaxial Locking Plate System	HRS
K081759	NCB Polyaxial Locking Plate System, Proximal Humeral Plates	HRS
K061211	NCB Plating System, Proximal Tibia Plates	HRS
K042695	NCB Plating System	HRS
K120772	NCB PERIPROSTHETIC TROCHANTER PLATES AND SCREW	HRS
K100111	NCB Periprosthetic Femur Polyaxial Locking Plate System	HRS
K113718	NCB Straight Narrow Shaft Plates	HRS

Device Description Summary

21 CFR 807.92(a)(4)

NCB® Polyaxial Locking Plate System
The NCB (Non-Contact-Bridging) Polyaxial Locking Plate System is a plate solution intended for the treatment of fractures and

osteotomies of the distal femur (NCB DF), proximal humerus (NCB PH) and proximal tibia (NCB PT). NCB plate holes allow for polyaxial screw placement (30° cone) with subsequent screw locking. Before locking, the screws can act as lag screws and be used for fracture reduction. In the locked mode, the plates act as an internal fixator without contact between the plate and the bone surface reducing the risk of periosteal blood supply impairment.
An additional extension tuberculum minus plate can be assembled to the humeral plate with cerclage wire technique for fixation of anteroposterior (AP) tuberculum minus fractures. NCB femoral, humeral and tibial plates, cortical, cancellous and cannulated screws, locking cap, blind screw inserts and spacers are made from titanium alloy Protasul®-64 (Ti-6Al-4V - ISO 5832-3/ASTM F136). The tuberculum minus plate is made from cpTi (ISO 5832-2/ASTM F67), cortical screws from titanium alloy Protasul-100 (Ti-6Al-7Nb ISO 5832-11/ASTM F1295) and the cerclage wire from 1.4441 stainless steel Protasul-S (ISO 5832-1/ASTM F138-F139).
NCB® Periprosthetic Femur Plate System
The NCB (Non-Contact-Bridging) Periprosthetic Femur Plate System is a line of polyaxial locking plates for the treatment of femoral fractures, particularly of periprosthetic femoral fractures. The system consists of Proximal Femur Plates, Distal Femur Plates, Curved Shaft Plates, Trochanter Plates and a Connection Screw. The NCB System technology allows for polyaxial screw placement (30° cone) with screw locking achieved with the use of locking caps that are threaded into the plate holes. In the locked mode the NCB Periprosthetic Plate acts as an internal fixator without contact between the plate and the bone surface, reducing the risk of periosteal blood supply impairment. This Non-Contact Bridging concept can be specifically controlled through the use of 1, 2, or 3 mm spacers, which are threaded into the plate holes prior to plate insertion.
Additionally, within this system, the NCB Periprosthetic Trochanter Plates are locking plates used in combination with the NCB Periprosthetic Proximal Femur Plates for the treatment of proximal femoral fractures, which includes greater trochanter fractures and osteotomies. The Connection Screw for NCB Periprosthetic Trochanter Plate is used to attach the Trochanter Plate to the Proximal Femur Plate. The NCB Periprosthetic Trochanter Plates contain threaded conical holes which allow for monoaxial screw placement using locking screws with threaded heads. Non-locking cortical screws can also be used.
The NCB Periprosthetic Proximal Femur Plates are available in five lengths (Length=245mm, 285mm, 324mm, 363mm, 401mm) which can be used either as standalone implants or in combination with the NCB Periprosthetic Trochanter Plates. The NCB Periprosthetic Proximal Femur Plate short (Length=115 mm) is used only in combination with the NCB Periprosthetic Trochanter Plates.
The NCB Curved Shaft Plates are also included in the NCB Periprosthetic Femur Plate System and are specifically designed for the femur.
The Proximal Femur Plates, Distal Femur Plates, Curved Shaft Plates, Trochanter Plates and Connection Screw are made of a titanium alloy (Ti-6Al-4V (Protasul®-64WF) ISO 5832-3).
NCB Cable Button for NCB Polyaxial Locking Plate
The NCB (Non-Contact-Bridging) Cable Button for NCB Polyaxial Locking Plate is a temporary internal fixation component used in conjunction with Zimmer Biomet NCB Polyaxial Locking Plate System and Cable-Ready System Cerclage Cables. The Cable Button is threaded into a vacant screw hole of the Zimmer Biomet NCB Polyaxial Locking Plate System and provides a positioning point for a Cerclage Cable.
The Cable Button is made of titanium alloy (Ti-6Al-4V (Protasul®-64WF) ISO 5832-3) and has a color anodization (Type III).
NCB Straight Narrow Shaft Plate
The NCB (Non-Contact-Bridging) Straight Narrow Shaft Plate is a line of polyaxial locking plates for the treatment of humeral and tibial shaft fractures, including periprosthetic fractures. The NCB System technology allows for polyaxial screw placement (30° cone) with screw locking achieved with the use of locking caps that are threaded into the plate holes. In the locked mode the NCB Straight Narrow Shaft Plate acts as an internal fixator without contact between the plate and the bone surface, reducing the risk of periosteal blood supply impairment. This Non-Contact-Bridging concept can be specifically controlled through the use of 1, 2, or 3 mm spacers, which are threaded into the plate holes prior to plate insertion.
The NCB Straight Narrow Shaft Plate is made of Titanium alloy [Ti6Al4V (Protasul®-64WF) ISO 5832-3].

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

NCB® Polyaxial Locking Plate System:
The NCB Polyaxial Locking Plate System is indicated for temporary internal fixation and stabilization of distal femoral (NCB DF), proximal humeral (NCB PH), and proximal tibial (NCB PT) fractures and osteotomies.

NCB® Periprosthetic Femur Plate System:
The NCB Periprosthetic Femur Plate System is indicated for temporary internal fixation and stabilization of femoral fractures and osteotomies, including periprosthetic fractures.

If combined with the NCB Periprosthetic Trochanter Plate and Connection Screw, the NCB Periprosthetic Proximal Femur Plate is additionally indicated for temporary internal fixation and stabilization of greater trochanter fractures and osteotomies including re-attachment of the greater trochanter following fracture and osteotomy in total hip arthroplasty.

The NCB Periprosthetic Trochanter Plate and Connection Screw can only be used in combination with the NCB Periprosthetic Proximal Femur Plate.

NCB® Cable Button:
The NCB Cable Button for the NCB Polyaxial Locking Plate System in combination with the Zimmer Biomet NCB Polyaxial Locking Plate System and Cable-Ready System Cerclage Cables is indicated for temporary internal fixation of fractures and osteotomies.

NCB® Straight Narrow Shaft Plate
The NCB Straight Narrow Shaft Plate is indicated for temporary internal fixation and stabilization of humeral and tibial shaft fractures and osteotomies, including periprosthetic fractures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications are similar between the predicate and the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

Comparison of Technological Characteristics:
The NCB Polyaxial Locking Plate System, The NCB Periprosthetic Femur Polyaxial Locking Plate System (including the Trochanter Plate and the Cable Button) and NCB Straight Narrow Shaft Plate are similar in intended use and identical in basic shape, material and performance characteristics to the predicate devices. There is no change in the fundamental scientific technology shared by both the subject device and predicate device and therefore the technological characteristics do not raise any new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Evaluation of MR compatibility to support MR Conditional labeling
•ASTM F2503-20 (Labeling)
•ASTM F2119-07R13 (Artifact)
•ASTM F2213-17 (Torque)
•ASTM F2052-21 (Displacement Force)
•ASTM F2182-19E02 (RF-heating) – Preliminary Phantom Eval.

Clinical data and conclusions were not needed for this device.

The subject devices have identical intended use and identical 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 to the labeling 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 different questions of safety and effectiveness as established with performance testing; and
•the subject devices are as safe and effective as the legally marketed predicate devices.