October 5, 2021

ChM sp. z o.o.
Boguslaw Krzywicki
Certification and Registration Specialist
Lewickie 3b
Juchnowiec Koscielny, Podlaskie 16-061
Poland

Re: K210490
Trade/Device Name: ChM 4.5mm Cortical screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 1, 2020
Received: February 19, 2021

Dear Boguslaw Krzywicki:

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, M.P.H.
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)*
K210490

Device Name
ChM 4.5mm Cortical screws

Indications for Use *(Describe)*
The ChM 4.5mm Cortical screws are intended for fixation of various long bones, such as the humerus, femur and tibia. They are also for use in fixation of non-unions or malunions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.

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

Company	ChM sp. z o.o. Lewickie 3b, 16-061 Juchnowiec Kościelny Tel: + 48 85 86 86 100; Fax: + 48 85 86 86 101
Contact	Bogusław Krzywicki Certification and Registration Specialist ChM sp. z o.o. Tel: + 48 85 86 86 306; Fax: + 48 85 86 86 101 Email: boguslaw.krzywicki@chm.eu
Date Prepared	September 29, 2021

NIP 966-11-76-019
REGON 050561656
BDO: 000002928
Sąd Rejonowy w Białymstoku
XII Wydział Gospodarczy: KRS 0000187570
Wysokość kapitału zakładowego 9 050 000 zł

Device Trade Name	ChM 4.5mm Cortical screws
510k number	K210490
Device Common Name	Bone screws
Classification Name:	Smooth or threaded metallic bone fixation fastener (21 C.F.R. 888.3040)
Product Code	HWC
Predicate Device(s)	ChM 4.5mm Cortical screws were shown to be substantially equivalent to the: K112583 – Synthes Cortical Screws Substantial equivalence for ChM 4.5mm Cortical screws is based on its similarities in: material, design features, indications for use, patient population, performance requirements, and operational principles when compared to the predicate devices cleared under the above-mentioned submission.
Device Description	This Traditional 510(k) submission is being supplied to the U.S. FDA to seek clearance to market the new ChM 4.5mm Cortical screws. The ChM 4.5mm Cortical screws are single-use, stand alone, open reduction and internal fixation devices. They have self-tapping features, hexdrive head recess, and are manufactured from titanium alloy in accordance with ISO 5832-11/ ASTM F1295-16. The ChM 4.5mm Cortical screws are offered non-sterile only and are available in various lengths. The device is meant to be used as a load sharing device, and it may be removed once the fracture is healed. Implantation with use of cortical screws should be performed in the operating room conditions.

Intended use and Indications for Use	The ChM 4.5mm Cortical screws are intended for fixation of various long bones, such as the humerus, femur and tibia. They are also for use in fixation of non-unions or malunions in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by screw fixation.
Comparison of Technological characteristics with the Predicate Device	The ChM 4.5mm Cortical screws have similar technological characteristics to the identified predicate. The material, design features, indications for use, patient population, performance requirements, and operational principles are equivalent to the predicate device. A review of the test data for the subject devices indicates that they are capable of withstanding expected in vivo loading without failure.
Performance Data	**Non-clinical Testing** Non-clinical, biomechanical testing as specified in the ASTM F543 – 17 was performed on the ChM 4.5mm Cortical screws to determine substantial equivalence. Testing demonstrated that the ChM 4.5mm Cortical screws are substantially equivalent to the predicate device currently cleared for marketing. Safety in MRI Not Evaluated. **Biocompatibility Testing** The biocompatibility evaluation (ISO 10993-1 Fifth edition 2018-08) was performed to evaluate the biological safety of ChM 4.5mm Cortical screws according to FDA Guidance: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".* According to ISO 10993-1 Annex A, the implants belong to „Implant medical device" category, principally contacting tissue and bone, duration of contact exceeds 30 days (long term contact). The material is titanium alloy as per ISO 5832-11/ ASTM F1295-16.

	ChM 4.5mm Cortical screws are biocompatible. **Animal Testing** Animal testing was not required for this submission. **Clinical Testing** Clinical testing was not required for this submission.
Substantial Equivalence Conclusion	Based upon a comparison of the material, design features, indications for use, patient population, performance requirements, and operational principles, the subject ChM 4.5mm Cortical screws are substantially equivalent to the predicate device identified in this premarket notification. ChM 4.5mm Cortical screws manufactured by ChM sp. z o.o. proved to perform at least as well as the predicate device.