FH Industrie
% Kathy L. Remsen, MS, MBA, CTBS
Principal Consultant
MRC Global
9085 East Mineral Circle, Suite 110
Centennial, CO 80112
USA

October 1, 2020

Re: K200127
Trade/Device Name: TELEGRAPH® EVOLUTION Humeral Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 1, 2020
Received: September 1, 2020

Dear Kathy Remsen:

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,

For Michael Owens
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K200127

Device Name
TELEGRAPH® EVOLUTION Humeral Nailing System

Indications for Use *(Describe)*
Fracture of the proximal extremity of the humerus.
Fracture of the diaphysis of the humerus.

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
FH Industrie TELEGRAPH® EVOLUTION Humeral Nailing System
October 1, 2020

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Trade Name: TELEGRAPH® EVOLUTION Humeral Nailing System

Common Name: Rod, Fixation, Intramedullary and Accessories

Classification: Class II

Regulation Number: 21 CFR 888.3020 (Intramedullary fixation rod)

Panel: Orthopedic

Product Code: HSB

Device Description:
The FH Industrie TELEGRAPH® EVOLUTION Humeral Nailing System includes short and long intramedullary cannulated humeral nails with right and left orientations, proximal screws, distal screws and a washer. The nails, screws, and washer are intended for use in treatment of fracture of the proximal extremity of the humerus or fracture of the diaphysis of the humerus. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI). The nails that are the subject of this submission are cannulated.

Indications for Use:
Fracture of the proximal extremity of the humerus.
Fracture of the diaphysis of the humerus.

Substantial Equivalence:

The subject TELEGRAPH® EVOLUTION Humeral Nailing System components are substantially equivalent with respect to indications for use, design, dimension, and materials to the following devices, previously cleared by the FDA:

Primary Predicate:

- FH Industrie: Modification to TELEGRAPH® HUMERAL NAIL – K033510

Secondary Predicates:

- FH Industrie: TELEGRAPH® HUMERAL NAIL– K023241
- FH Industrie: TITANIUM TELEGRAPH® HUMERAL NAIL – K042332
- Tornier: AEQUALIS HUMERAL NAIL SYSTEM – K133376

Reference Devices (Biocompatibility predicates):
-FH Industrie: CALCANAIL Orthopedic Nail – K150463
-FH Industrie: CALCANAIL Orthopedic Arthrodesis Nail -- K150471

Comparison of Technological Characteristics:

The Indications for Use, Materials, and Geometry for predicate devices are all similar to those of the subject device. The indication of both the subject and predicate devices include the treatment of proximal and diaphyseal fractures of the humerus. Although the material of the subject device is different than that of the primary predicate, it is identical to the material of the secondary predicates. The subject device is of similar geometry to the predicate devices and is offered in a range of sizes as that is within the size range of the predicate devices. However, unlike the primary predicate, the subject humeral nail is cannulated. Comparison of mechanical test results of the worst case subject cannulated nail to the worst case predicate device showed substantially equivalent results. Thus, it can be concluded that the subject device does not raise new questions about safety and effectiveness.

Performance Testing:

Sterilization (ISO 11137), packaging (ISO 11607), and biocompatibility (ISO 10993-1) validations and rationales were conducted and provided to demonstrate substantial equivalence. Bacterial endotoxin levels were evaluated using LAL pyrogen testing.

Mechanical testing has been performed per ASTM F1264 and ASTM F543 on the subject TELEGRAPH® EVOLUTION Humeral Nailing System and the results have shown them to be substantially equivalent to the predicate device.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.