Globus Medical Inc.
Jennifer Antonacci
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

September 9, 2022

Re: K220659
Trade/Device Name: AUTOBAHN® EVO Femoral Nails
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDS, HTN, HWC
Dated: August 12, 2022
Received: August 12, 2022

Dear Jennifer Antonacci:

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 Victoria Lilling, M.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220659

Device Name
AUTOBAHN® EVO Femoral Nails

Indications for Use *(Describe)*

AUTOBAHN® EVO Femoral Nails are indicated for long bone fracture fixation in skeletally mature patients, specifically femoral fracture fixation, which may include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, supracondylar fractures, including those with intra-articular extension, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee arthroplasty, fractures distal to hip joint, nonunions and malunions, poly trauma patients, fractures in the morbidly obese, fractures involving osteopenic and osteoporotic bone, compound and simple shaft fractures, proximal, metaphyseal, and distal shaft fractures, segmental fractures, closed supracondylar fractures, fractures involving femoral condyles, comminuted fractures, fractures with bone loss, and periprosthetic fractures. In addition, the AUTOBAHN® EVO Antegrade Nails are intended for use in adolescents (12-21 years) in which the growth plates have fused.

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: AUTOBAHN® EVO Femoral Nails

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Contact: Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

Date Prepared: September 7, 2022

Device Name: AUTOBAHN® EVO Femoral Nails

Common Name: Intramedullary fixation rod
Single/multiple component metallic bone fixation appliances and accessories
Smooth or threaded metallic bone fixation fastener

Classification: Per 21 CFR as follows:
§888.3020 Intramedullary fixation rod (primary)
§888.3030 Single/multiple component metallic bone fixation appliances and accessories
§888.3040 Smooth or threaded metallic bone fixation fastener
Product Code: HSB (primary), JDS, HWC
Regulatory Class: II, Panel Code: 87

Primary Predicate: AUTOBAHN® Nailing System (K171108)

Additional Predicates: DePuy Synthes Retrograde Femoral Nail Advanced System, Locking Screws for Medullary Nails, 5.0 mm (K201346)
DePuy Synthes Femoral Recon Nail System (K172157)

Purpose:
The purpose of this submission is to request clearance for additional AUTOBAHN® EVO Femoral Nails as a line extension to the AUTOBHAN® Nailing System.

Device Description:
The AUTOBAHN® Nailing System is a family of intramedullary nails, screws and washers designed to be used for internal bone fixation. The AUTOBAHN® EVO implants include femoral nails (antegrade and retrograde) and locking screws available in various lengths and diameters to accommodate a wide range of patient anatomy; the nails are secured with locking screws. Washers and nuts are also

available. Devices are manufactured from titanium alloy, cobalt chrome alloy, and stainless steel.

Indications for Use:
AUTOBAHN® EVO Femoral Nails are indicated for long bone fracture fixation in skeletally mature patients, specifically femoral fracture fixation, which may include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, supracondylar fractures, including those with intra-articular extension, ipsilateral hip/shaft fractures, ipsilateral femur/tibia fractures, fractures proximal to a total knee arthroplasty, fractures distal to hip joint, nonunions and malunions, poly trauma patients, fractures in the morbidly obese, fractures involving osteopenic and osteoporotic bone, compound and simple shaft fractures, proximal, metaphyseal, and distal shaft fractures, segmental fractures, closed supracondylar fractures, fractures involving femoral condyles, comminuted fractures, fractures with bone loss, and periprosthetic fractures. In addition, the AUTOBAHN® EVO Antegrade Nails are intended for use in adolescents (12-21 years) in which the growth plates have fused.

Performance Data:
Mechanical testing (static and dynamic four-point bending and static torsion) was conducted in accordance with ASTM F1264. Screw testing per ASTM F543, screw cutout testing, and locking washer construct testing was also conducted. Performance data demonstrate substantial equivalence to the predicate devices.

Technological Characteristics:
The AUTOBAHN® EVO implants have similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes. The subject AUTOBAHN® EVO nails have specific antegrade and retrograde designs, while the predicate AUTOBAHN® Antegrade/Retrograde (A/R) nails accommodate both approaches in one design. These differences are minor and do not raise any different questions of safety or effectiveness for the AUTOBAHN EVO device for its intended indications for use.

Conclusions:
The AUTOBAHN® EVO Femoral Nails have been found to be substantially equivalent to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket submission supports substantial equivalence of the subject implants to the predicate devices.