January 12, 2018

Globus Medical Inc.
Kelly Baker
Senior Vice President/Regulatory and Clinical Affairs
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K172438
Trade/Device Name: ARBOR External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, LXT
Dated: December 12, 2017
Received: December 13, 2017

Dear Kelly Baker:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K172438

Device Name
ARBOR™ External Fixation System

Indications for Use *(Describe)*
The ARBOR™ External Fixation System is indicated for use in construction of an external fixation frame for the treatment of pediatric and adult fractures and/or reconstruction of long bones, small bones (including metacarpal and metatarsal), and the pelvis.

The ARBOR™ External Fixation System is intended for:
- Stabilization of open or closed fractures with soft tissue injuries;
- Polytrauma;
- Vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures;
- Arthrodesis and osteotomies with soft tissue problems;
- Revision procedures where other devices have been unsuccessful including failures of total joints;
- Neutralization of fractures stabilized with limited internal fixation;
- Non-unions/septic non-unions;
- Intraoperative reduction/stabilization tool to assist with indirect reduction;
- Correction of deformity; and
- Unilateral rectilinear bone segment transport or leg lengthening.

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: ARBOR™ External Fixation System

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

Contact: Kelly J. Baker, Ph.D.
Senior Vice President, Regulatory and Clinical Affairs

Date Prepared: January 9, 2018

Device Name: ARBOR™ External Fixation System

Common Name: External Fixation System

Classification: Per 21 CFR as follows:
§888.3030 Single/multiple component metallic bone fixation appliances and accessories
Product Codes: KTT, LXT
Regulatory Class: II, Panel Code: 87

Primary Predicate: Synthes Large External Fixation System (K031428)

Additional Predicates: Gexfix External Fixation System (K052605 & K160972)
SBi Mini Rail External Fixation System (K093550)
Stryker Hoffmann 3 (K122284) & Apex Pins (K061493)
Synthes Medium External Fixation System (K040258)

Purpose:
The purpose of this submission is to request clearance for the ARBOR™ External Fixation System.

Device Description:
The ARBOR™ External Fixation System is comprised of Schanz pins, external fixation clamps, and bars. The pins and bars are available in various sizes, and the fixation clamps are available in several designs all capable of use with any size pins and bars.

Indications for Use:
The ARBOR™ External Fixation System is indicated for use in construction of an external fixation frame for the treatment of pediatric and adult fractures and/or reconstruction of long bones, small bones (including metacarpal and metatarsal), and the pelvis.

The ARBOR™ External Fixation System is intended for:

- Stabilization of open or closed fractures with soft tissue injuries;
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- Revision procedures where other devices have been unsuccessful including failures of total joints;
- Neutralization of fractures stabilized with limited internal fixation;
- Non-unions/septic non-unions;
- Intraoperative reduction/stabilization tool to assist with indirect reduction;
- Correction of deformity; and
- Unilateral rectilinear bone segment transport or leg lengthening.

Performance Data:
Performance of the ARBOR™ External Fixation System was evaluated in accordance with ASTM F543 and F1541. Engineering analysis and mechanical testing of pins, bars, and clamps was performed, including insertion torque, pullout, static torsion, and static axial compression. Performance data demonstrates substantial equivalence to the predicate devices.

Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011. Biocompatibility of patient-contacting materials was demonstrated by using materials that meet applicable standards or are used in 510(k) cleared devices. MRI testing was performed on the subject devices per ASTM F2052, F2182, and F2213.

Technological Characteristics:
The ARBOR™ External Fixation System implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Conclusions:
The ARBOR™ External Fixation System has 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 notification supports substantial equivalence to the predicate devices.