DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 7, 2017

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

Re: K163361
Trade/Device Name: Anthem™ Fracture System
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: March 8, 2017
Received: March 9, 2017

Dear Dr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163361

Device Name
ANTHEM™ Fracture System

Indications for Use *(Describe)*
The ANTHEM™ Fracture System is indicated for fixation of fractures, osteotomies, arthrodesis and reconstruction of bones for the appropriate size of the device to be used in adult patients, including the clavicle, scapula, humerus, radius, ulna, small bones (metacarpals, metatarsals, phalanges), wrist, pelvis, femur, tibia, fibula, ankle, and foot. Small fragment and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius plates may be used in adolescents (12-21 years of age).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: ANTHEM™ Fracture 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: April 6, 2017

Device Name: ANTHEM™ Fracture System

Common Name: Bone plate & screws

Classification: Per 21 CFR as follows:
§888.3030 Single/multiple component metallic bone fixation appliance and accessories
§888.3040 Smooth or threaded metallic bone fixation fastener
Product Code: HRS, HWC
Regulatory Class: II

Predicates:
Synthes 2.7mm/3.5mm LCP Distal Fibula Plates (K073460)
Arthrex Fracture System (K112437)
Synthes Volar Distal Radius Plate (K092556, K982732)
Stryker Anatomic Volar Plate (K133974)
Skeletal Dynamics Geminus Volar Distal Radius Plate System (K111620)
Trimed Bearing Bridge Plate (K040112)
Medartis Hook Plate (K142906)
Synthes LCP Distal Radius System (K102694)
Synthes LCP Proximal Humerus Plates (K011815, K041860)
Arthrex Humeral Fracture Plate (K041965)
Synthes 3.5mm LCP Periarticular Proximal Humerus Plates (K082625)
Biomet Proximal Humerus Plating System (K143697)
Synthes Small Fragment DCL System (K000684)
Stryker Plating System (K060514)
PERI-LOC Plating and Screw System (K083032)
Arthrex Fracture System (K112437)
OrthoPediatrics PediLoc Locking Plate System (K083286)
Synthes Modular Mini Fragment LCP (K063049)
GPC BRAND Locking Bone Plates and Screws (K153716)
Synthes Large Fragment DCL System (K000682)

EVOS Mini-Fragment Plating System (K140814)
TriMed Volar Buttress Pin (K951303)
AFT GTF System (K133668)
Modified Shoulder Fixation System (K060290)
Synthes LCP Dia-Meta Volar Distal Radius Plates (K070946)

Purpose:
The purpose of this submission is to request clearance for the ANTHEM™ Fracture System.

Device Description:
The ANTHEM™ Fracture System is a family of plates and screws designed to be used for internal bone fixation. The implants are available in various sizes and shapes to accommodate patient anatomy, and may be contoured or straight, sterile and non-sterile, with locking and non-locking screws. ANTHEM™ implants are manufactured from medical grade titanium alloy, cobalt chromium molybdenum alloy, or stainless steel. All implants are for single use only.

Indications for Use:
The ANTHEM™ Fracture System is indicated for fixation of fractures, osteotomies, arthrodesis and reconstruction of bones for the appropriate size of the device to be used in adult patients, including the clavicle, scapula, humerus, radius, ulna, small bones (metacarpals, metatarsals, phalanges), wrist, pelvis, femur, tibia, fibula, ankle, and foot. Small fragment and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius plates may be used in adolescents (12-21 years of age).

Performance Data:
Performance of the ANTHEM™ Fracture System plates and screws were evaluated in accordance with ASTM F543, F382, and F2193. Engineering analysis and bending strength tests were conducted for the plates and screws, and pullout strength and insertion/removal torque tests were conducted for the screws. Performance data demonstrates substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

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

Basis of Substantial Equivalence:
The subject ANTHEM™ Fracture 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.