



January 26, 2022

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

Re: K213591

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, HTN

Dated: November 11, 2021

Received: November 12, 2021

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,

Shumaya Ali, MPH
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

Indications for Use

510(k) Number (if known)

K213591

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. The clavicle hook plate may be used for dislocations of the acromioclavicular joint. Distal femur plates are indicated for diaphyseal, metaphyseal, epiphyseal, supracondylar, intra-articular, extra-articular, condylar, periprosthetic, and comminuted fractures, and for non-unions and malunions. Mini fragment plates are also indicated for fixation of fractures of the acetabulum, patella, and bone fragments, replantation, malunions and nonunion, and for non-load bearing stabilization and reduction of long bone fragments. Metaphyseal plates are indicated for non-load bearing stabilization and reduction of long bone fragments, and for fixation of bones including the radius and ulna.

In addition to adult patients, small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates are indicated for use in infant, child, and adolescent pediatric subgroups and small stature adults. Distal femur plates are indicated for use in the diaphyseal and metaphyseal areas of long bones in adolescent pediatric patients. Distal radius, distal tibia, metaphyseal, and mini fragment plates are indicated for use in adolescents (12-21 years of age). Plating can be used in patients with osteopenic bone.

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: ANTHEM® Fracture System

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: January 26, 2022

Device Name: ANTHEM® Fracture System

Common Name: Bone plates, screws, & washers

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

Primary Predicate: ANTHEM® Fracture System (K202496)

Additional Predicates: ANTHEM® Fracture System (K212433)
Stryker AxSOS 3 (K172350)

Purpose:

The purpose of this submission is to request clearance for ANTHEM® Distal Femur plates, screws, and washers, as a line extension to the ANTHEM Fracture System.

Device Description:

The ANTHEM® Fracture System is a family of plates, screws, and washers designed to be used for internal bone fixation. The ANTHEM® Distal Femur implants are designed for fractures of the distal femur, and are available in various sizes and configurations to accommodate patient anatomy. The ANTHEM® implants are manufactured from titanium, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537, F2229, F138 and F139.

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. The clavicle hook plate may be used for dislocations of the acromioclavicular joint. Distal femur plates are indicated for diaphyseal, metaphyseal, epiphyseal, supracondylar, intra-articular, extra-articular, condylar, periprosthetic, and comminuted fractures, and for non-unions and malunions. Mini fragment plates are also indicated for fixation of fractures of the acetabulum, patella, and bone fragments, replantation, malunions and nonunion, and for non-load bearing stabilization and reduction of long bone fragments. Metaphyseal plates are indicated for non-load bearing stabilization and reduction of long bone fragments, and for fixation of bones including the radius and ulna.

In addition to adult patients, small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates are indicated for use in infant, child, and adolescent pediatric subgroups and small stature adults. Distal femur plates are indicated for use in the diaphyseal and metaphyseal areas of long bones in adolescent pediatric patients. Distal radius, distal tibia, metaphyseal, and mini fragment plates are indicated for use in adolescents (12-21 years of age). Plating can be used in patients with osteopenic bone.

Performance Data:

An engineering analysis was conducted for the plates to demonstrate substantial equivalence to the predicate devices. Performance of the ANTHEM® Fracture System screws were evaluated in accordance with ASTM F543 and the FDA guidance *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway* to demonstrate 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. In addition, the manufacturing methods are the same as those used in 510(k) cleared devices.

Technological Characteristics:

Subject ANTHEM® implants have similar technological characteristics as the predicate devices including overall 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 supports substantial equivalence to the predicate devices.