October 29, 2020

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

Re: K202496
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: August 28, 2020
Received: August 31, 2020

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, M.P.H.
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

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)*
K202496

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. 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.

Small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius, distal tibia, metaphyseal, and mini fragment plates may be used in adolescents (12-21 years of age). Plating may 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.**

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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:** Jennifer Antonacci, Ph.D.
Group Manager, Regulatory Affairs

**Date Prepared:** October 29, 2020

**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 (primary)
§888.3040 Smooth or threaded metallic bone fixation fastener
Product Code: HRS, HWC
Regulatory Class: II

**Primary Predicate:** ANTHEM® Fracture System (K163361)

**Additional Predicates:** ANTHEM® Fracture System (K173166, K180554)

**Purpose:**
The purpose of this submission is to request clearance for ANTHEM® Distal Tibia plates and other line extensions to the cleared 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, with various lengths and types of screws. ANTHEM® implants are manufactured from commercially pure titanium, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel.

**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. 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.

Small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius, distal tibia, metaphyseal, and mini fragment plates may be used in adolescents (12-21 years of age). Plating may be used in patients with osteopenic bone.

**Performance Data:**
Performance of the subject ANTHEM® Fracture System plates was evaluated in accordance with ASTM F382. Engineering analysis was conducted 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.

**Technological Characteristics:**
Subject ANTHEM® implants have similar technological characteristics as the predicate devices including overall design (prominence and footprint), intended use, material composition, and function. New Distal Tibia and Mini Fragment plates were added. Sterile implant options were added for consistency. Plates and screws fall within the range of previously cleared sizes; the plates are also compatible with previously cleared screws. New material specifications for existing plates are in accordance with the same material standards.

**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.