



August 18, 2025

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

Re: K251161

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: July 30, 2025
Received: July 30, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K251161

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Please provide the device trade name(s).

?

ANTHEM® Fracture System

Please provide your Indications for Use below.

?

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, distal humerus, proximal ulna, and proximal radius 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, distal humerus, proximal ulna, proximal radius, 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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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.
Director, Regulatory Affairs

Date Prepared: April 14, 2025

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 (primary), HWC
Regulatory Class: II, Panel Code: 87

Primary Predicate: ANTHEM® Fracture System (K163361)

Additional Predicates: ANTHEM® Fracture System (K202496, K212433,
K213591)
Synthes Variable Angle LCP™ Elbow System (K120070)

Reference Devices: HEDRON® Cervical & Lumbar Spacers, SABLE®
Expandable Spacer (K222270)

Purpose:

The purpose of this submission is to request clearance for ANTHEM® Distal Humerus, Proximal Ulna, and Proximal Radius plates 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 implants are available in various sizes and shapes, and may be contoured or straight, with various lengths to accommodate patient anatomy. The subject ANTHEM® plates are manufactured from titanium alloy per ASTM F136 or stainless steel as specified in ASTM F138 and F139. Plates are also available additively manufactured from titanium alloy powder per ASTM F3001.

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, distal humerus, proximal ulna, and proximal radius 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, distal humerus, proximal ulna, proximal radius, 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, and mechanical testing (static and dynamic four point bending) was conducted in accordance with ASTM F382 to demonstrate substantial equivalence to the predicate devices.

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. The subject ANTHEM® implants differ only in manufacturing method for the additively manufactured plates, which is identical to the reference device. This difference has been evaluated and does not raise any new concerns of safety or effectiveness for the subject ANTHEM® Fracture System for its intended indications for use.

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.