August 4, 2023

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

Re: K231333
Trade/Device Name: STRETTO™ Cable System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: JDQ, HWC, HRS
Dated: May 8, 2023
Received: May 8, 2023

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231333

Device Name
STRETTO™ Cable System

Indications for Use *(Describe)*
The STRETTO™ Cable System is indicated for use in: general orthopedic trauma surgery (e.g., fractures of the olecranon, patella, femur - including periprosthetic, pelvis, acetabulum, humerus and ankle, and acromioclavicular dislocations); prophylactic banding during total joint procedures; and, temporary reduction techniques for ORIF (Open Reduction Internal Fixation) procedures.

STRETTO™ Screw Anchors are indicated for fractures that may not be securely held by either a screw or a cerclage device alone, and where cerclage is used in combination with bone screws and/or plates to provide internal fixation of fractured bone.

STRETTO™ Press-In Anchors are indicated for use with a cerclage cable and plate to augment long bone fracture fixation, particularly when the use of screws would be inhibited, as in the presence of intramedullary implants.

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.

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510(k) Summary: STRETTO™ Cable 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: August 3, 2023

Device Name: STRETTO™ Cable System

Common Name: Bone fixation cerclage cable

Classification: Per 21 CFR as follows:
§888.3010 Bone Fixation Cerclage (primary)
§888.3030 Single/multiple component metallic bone fixation appliances and accessories
§888.3040 Smooth or threaded metallic bone fixation fastener

Product Code: JDQ (primary), HWC, HRS
Regulatory Class: II

Primary Predicate: Pioneer Laboratories SDB Cerclage System (K992616)

Additional Predicates: Pioneer Laboratories Hex Button Device (K992617)
Synthes Variable Angle Positioning Pins (K162124)

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

Device Description:
The STRETTO™ Cable System implants are comprised of cables, crimps and anchors. Anchors include a thru hole for the cables to pass through, and are available in multiple styles. Press-in anchors mate with ANTHEM fracture plates and screw anchors mate with the hex recess of ANTHEM screws. The cable is secured with the crimp and may be used with the anchors. STRETTO™ Implants are manufactured from titanium alloy, commercially pure titanium, cobalt chromium alloy, cobalt chromium molybdenum alloy, or stainless steel.

Indications for Use:
The STRETTO™ Cable System is indicated for use in general orthopedic trauma surgery, including olecranon, patella, femur (including periprosthetic fractures), pelvic, acetabular, humeral and ankle fractures, acromioclavicular dislocations, prophylactic banding during total joint procedures, and temporary reduction techniques for ORIF (Open Reduction Internal Fixation) procedures.

STRETTO™ Screw Anchors are indicated for fractures that may not be securely held by either a screw or a cerclage device alone, and where cerclage is used in combination with bone screws and/or plates to provide internal fixation of fractured bone.

STRETTO™ Press-In Anchors are indicated for use with a cerclage cable to augment fracture stabilization with plates used in long bone fixation, and when the use of screws would be inhibited, as in the presence of intramedullary implants.

Performance Data:
Mechanical testing (static and dynamic tension) was conducted using ASTM E8 as a guide. Performance data demonstrate substantial equivalence to the predicate devices. An engineering analysis was conducted for the anchors to demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST72:2011.

Technological Characteristics:
The STRETTO™ Cable System has similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:
The STRETTO™ Cable 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 of the subject devices to the predicate devices.