June 3, 2024

Globus Medical, Inc
Jennifer Antonacci
Senior Group Manager, Regulatory Affairs
Valley Forge Business Center
2560 General Armistead Ave
Audubon, Pennsylvania 19403

Re: K240947
Trade/Device Name: TENSOR® Suture Button System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: April 5, 2024
Received: April 8, 2024

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.

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.06.03 12:25:17 -04'00'

Jesse Muir, Ph.D.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240947

Device Name
TENSOR® Suture Button System

Indications for Use *(Describe)*
The TENSOR® Suture Button System is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the TENSOR® implants are intended to provide fixation during the healing process for the following indications:

Syndesmotic trauma, such as ankle syndesmosis fixation (syndesmosis disruptions), and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures; fixation of dorsal distal radioulnar ligament (DRUL) disruptions; Acromioclavicular separations due to coracoclavicular ligament disruptions; Tarsometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal-2nd metatarsal intermetatarsal angle; and, Carpal Metacarpal (CMC) joint arthroplasty as an adjunct in the healing process.

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.

510(k) Summary: TENSOR® Suture Button System

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Jennifer Antonacci, Ph.D.
Senior Group Manager, Regulatory Affairs

Secondary Contact: Suganya Gopalakrishnan
Regulatory Specialist

Date Prepared: May 31, 2024

Device Name: TENSOR® Suture Button System

Common Name: Button and suture fixation device

Classification: Per 21 CFR as follows:
§888.3030 Single/multiple component metallic bone fixation appliances and accessories
Product Code: HTN
Regulatory Class: II

Primary Predicate: Arthrex Syndesmosis TightRope XP Buttress Plate Implant System (K201522)

Additional Predicates: Arthrex Knotless Mini Tightropes (K213644)
ToggleLoc System (K173278)

Purpose:
The purpose of this submission is to request clearance for the TENSOR® Suture Button System.

Device Description:
The TENSOR® Suture Button System consists of metal buttons, a polymer suture, an optional washer, and instruments. The buttons are available in various sizes to accommodate varying patient anatomy and surgical needs. The buttons and washer are manufactured from titanium alloy or stainless steel, and the suture is manufactured from ultra high molecular weight polyethylene (UHMWPE) and polyethylene terephthalate (PET). The implants are sterile packaged with various instruments to aid in insertion.

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Performance Data:
Mechanical testing (static and dynamic tension) was conducted. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST72:2011. Performance data demonstrates substantial equivalence to the predicate devices.

Technological Characteristics:
The TENSOR® implants have similar technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes. The subject TENSOR round buttons differ in the number of apertures to route the suture, and the suture has a slightly different splice style and length as compared to the predicates. These differences are minor and do not raise any different questions of safety or effectiveness for the subject TENSOR device for its intended indications for use.

Basis of Substantial Equivalence:
The TENSOR® Suture Button 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 of the subject implants to the predicate devices.