September 8, 2022

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

Re: K222409
Trade/Device Name: CAPTIVATE® Compression Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 9, 2022
Received: August 10, 2022

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222409

Device Name
CAPTIVATE® Compression Screws

Indications for Use *(Describe)*

CAPTIVATE® Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

CAPTIVATE® VL Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of the phalanges, metacarpals, carpals, metatarsals, midfoot, hind foot, ankle, fibula, distal tibia, proximal tibia, radius, ulna, humerus, and clavicle.

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.

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510(k) Summary: CAPTIVATE® Compression Screws

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: September 8, 2022

Device Name: CAPTIVATE® Compression Screws

Common Name: Bone screws

Classification: Per 21 CFR as follows:
§888.3040 Smooth or threaded metallic bone fixation fastener
Product Code: HWC
Regulatory Class: II

Primary Predicate: CAPTIVATE® Compression Screws (K162825)

Other Predicates: Zimmer Biomet Cannulated Screw System (K140891)
Paragon 28 Monster® Screw System (K190586)

Reference Device: ANTHEM® Fracture System (K212433)

Purpose:
The purpose of this submission is to request clearance for new implants and changes for CAPTIVATE® Compression Screws.

Device Description:
CAPTIVATE® Compression Screws consist of bone screws designed to compact juxtaposed bone for reconstruction and enhanced arthrodesis. The implants are available in various diameters and lengths to accommodate patient anatomy, with headless, partially or fully threaded, solid or cannulated, and variable length (VL) options. CAPTIVATE® implants are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537, and F138.

Indications for Use:
CAPTIVATE® Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

CAPTIVATE® VL Compression Screws are indicated for use in adult and pediatric patients, for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of the phalanges, metacarpals, carpals, metatarsals, midfoot, hind foot, ankle, fibula, distal tibia, proximal tibia, radius, ulna, humerus, and clavicle.

Performance Data:
Performance of the CAPTIVATE® Compression Screws was evaluated in accordance with ASTM F543, ASTM F2193, and the FDA guidance *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*. Static torsion, insertion/removal, axial pullout, and cantilever bending testing was conducted 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 (K162825, K212433).

Technological Characteristics:
Subject CAPTIVATE® implants have similar technological characteristics as the predicate devices including overall design, intended use, material composition, function, and range of sizes. New material specifications for existing screws are in accordance with the same material standards.

Basis of Substantial Equivalence:
The subject CAPTIVATE® Compression Screws have 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.