



December 16, 2019

Globus Medical Inc.  
Kelly J. Baker, Ph.D.  
Senior Vice President, Regulatory and Clinical Affairs  
2560 General Armistead Avenue  
Audubon, Pennsylvania 19403

Re: K192744  
Trade/Device Name: CORRIDOR<sup>®</sup> Fixation System  
Regulatory Class: Unclassified  
Product Code: MRW, HWC  
Dated: September 27, 2019  
Received: September 30, 2019

Dear Dr. Baker:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean, Ph.D.  
Director (Acting)  
DHT6B: Division of Spinal Devices  
OHT6: Office of Orthopedic Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K192744

Device Name

CORRIDOR® Fixation System

*Indications for Use (Describe)*

The CORRIDOR® Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5mm and 4.0mm screws and from L1 to S1 for 4.5mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle.

The CORRIDOR® Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

The CORRIDOR® Fixation System is also indicated for fracture fixation of small bones and bone fragments including odontoid fractures.

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: CORRIDOR® Fixation System**

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

**Contact:** Kelly J. Baker, Ph.D.  
Senior Vice President, Regulatory and Clinical Affairs

**Date Prepared:** September 27, 2019

**Device Name:** CORRIDOR® Fixation System

**Common Name:** Smooth or threaded metallic bone fixation fastener

**Classification:** Per 21 CFR as follows:  
Unclassified, §888.3040 Smooth or threaded metallic  
bone fixation fastener  
Product Codes MRW, HWC  
Regulatory Class: Unclassified, II, Panel Code: 87

**Primary Predicate:** CORRIDOR® Fixation System (K083442)

**Additional  
Predicates:** Aesculap Odontoid Fracture Fixation System (K142707)  
DePuy Synthes Dens Access System (K132910)  
Skeletal Dynamics Headless Screw System (K143624)

**Purpose:**  
The purpose of this submission is to request clearance for additional indications for the CORRIDOR® Fixation System.

**Device Description:**  
The CORRIDOR® Fixation System consists of screws and instruments designed to aid in bone fixation. The screws are available partially threaded or fully threaded, cannulated or non-cannulated, and in various diameters and lengths to accommodate patient anatomy. Screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

**Indications for Use:**

The CORRIDOR® Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 3.5mm and 4.0mm screws and from L1 to S1 for 4.5mm screws. For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle.

The CORRIDOR® Fixation System is indicated for treatment of any or all of the following: pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity; spondylolisthesis; spondylolysis; degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; degeneration of the facets with instability and trauma including spinal fractures and/or dislocations.

The CORRIDOR® Fixation System is also indicated for fracture fixation of small bones and bone fragments including odontoid fractures.

**Performance Data:**

No mechanical testing was completed for this submission as these devices are previously cleared. 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:**

The CORRIDOR® Fixation system has the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

**Basis of Substantial Equivalence:**

The subject CORRIDOR® Fixation system implants are similar to the predicate devices with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.