July 29, 2022

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

Re: K181068
Trade/Device Name: CREO® Stabilization System, REVERE® Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Dr. Baker:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 29, 2018. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

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

June 29, 2018

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

Re: K181068
Trade/Device Name: CREO® Stabilization System, REVERE® Stabilization System
Regulatory Class: Unclassified
Product Code: PGM
Dated: June 14, 2018
Received: June 15, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181068

Device Name
CREO® Stabilization System

Indications for Use *(Describe)*
In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181068

Device Name
REVERE® Stabilization System

Indications for Use *(Describe)*
In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

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)

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510(k) Summary: CREO® and REVERE® Stabilization Systems

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: June 14, 2018

Device Name: CREO® Stabilization System
REVERE® Stabilization System

Classification: Pre-Amendment Device
Growing Rod System
Product Code: PGM
Regulatory Class: Unclassified

Primary Predicate: Medtronic CD HORIZON Growth Rod (K133904, K150200)

Additional Predicates: K2M Growing Spine System (K161028)
CREO® Stabilization System
(K124058, K153203, K172269, K180210)
REVERE® Stabilization System
(K061202, K091782, K113395, K133350)

Purpose:
The purpose of this submission is to request clearance for additional indications for CREO® and REVERE® in-line connectors for use in growing rod constructs.

Device Description:
CREO® Stabilization System
In-Line Connector Growing Rods consist of rod-to-rod connectors which can be surgically lengthened on a periodic basis as the patient grows. These connectors may be used as part of a growing rod construct consisting of rods, screws, hooks, offset connectors, and cross-connectors, and are limited to a posterior approach. When used as part of a growing rod system, In-Line Connector Growing Rods are intended for use only with CREO® Stabilization System fusion constructs cleared for pediatric use. In-Line Connector Growing Rods are manufactured from titanium alloy.

REVERE® Stabilization System
In-Line Connector Growing Rods consist of rod-to-rod connectors which can be surgically lengthened on a periodic basis as the patient grows. These connectors

may be used as part of a growing rod construct consisting of rods, screws, hooks, offset connectors, and cross-connectors, and are limited to a posterior approach. When used as part of a growing rod system, In-Line Connector Growing Rods are intended for use only with REVERE® Stabilization System fusion constructs cleared for pediatric use. In-Line Connector Growing Rods are manufactured from titanium alloy.

Indications for Use:

CREO® Stabilization System

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

REVERE® Stabilization System

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Summary of Technological Characteristics as Compared to the Predicates

The technological characteristics of the subject and predicate devices are identical.

Performance Data:

No mechanical testing, sterilization, biocompatibility, or endotoxin testing was completed for this submission as these devices are previously cleared.

Clinical Literature:

A clinical literature review was performed to support the use of the subject devices as growing rod constructs. The risks of growing rod use were identified and mitigated through design and surgical technique. Based on clinical literature, the safety profile of the subject devices is equivalent to that of the predicate devices.

Technological Characteristics:

Subject CREO® and REVERE® implants have 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 CREO® and REVERE® implants have the same intended use, similar indications for use, similar technological characteristics and design, same materials and the same principles of operation as predicate CD HORIZON Growth Rods and K2M Growing Spine System.