March 27, 2018

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

Re: K172269
Trade/Device Name: FORTRESS™ Radiopaque Bone Cement (FORTRESS™ and FORTRESS-Plus™), CREO® Fenestrated Screw System, REVLOK® Fenestrated Screw System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: PML, NKB, KWQ
Dated: March 15, 2018
Received: March 16, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K172269

Device Name
FORTRESS™ Radiopaque Bone Cement (FORTRESS™ and FORTRESS-Plus™)

Indications for Use *(Describe)*
FORTRESS™ Radiopaque Bone Cement (FORTRESS™ and FORTRESS-Plus™) is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with CREO® or REVLOK® Fenestrated Screw Systems for posterior fixation, FORTRESS™ Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. FORTRESS™ Radiopaque Bone Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

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."

Indications for Use

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

510(k) Number *(if known)*
K172269

Device Name
CREO® Fenestrated Screw System

Indications for Use *(Describe)*

CREO® Fenestrated Screw System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the CREO® Fenestrated Screw System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the CREO® Fenestrated Screw System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

When used for posterior fixation in conjunction with FORTRESS™ or FORTRESS-Plus™ bone cement, the CREO® Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CREO® Fenestrated screws augmented with FORTRESS™ or FORTRESS-Plus™ bone cement are intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

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)*
K172269

Device Name
REVLOK® Fenestrated Screw System

Indications for Use *(Describe)*
REVLOK® Fenestrated Screw System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVLOK® Fenestrated Screw System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVLOK® Fenestrated Screw System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

When used for posterior fixation in conjunction with FORTRESS™ or FORTRESS-Plus™ bone cement, the REVLOK® Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. REVLOK® Fenestrated screws augmented with FORTRESS™ or FORTRESS-Plus™ bone cement are intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

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: **CREO® and REVLOK® Fenestrated Screw and FORTRESS™ and FORTRESS-Plus™ Bone Cements for Cement Augmentation**

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

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

Date Prepared: March 15, 2018

Device Name: 1) FORTRESS™ Radiopaque Bone Cement
(FORTRESS™ and FORTRESS-Plus™)
2) CREO® Fenestrated Screw System
REVLOK® Fenestrated Screw System

Classification: 1) Per 21 CFR as follows:

§888.3027 Bone Cement, Posterior Screw Augmentation

Product Codes PML
Regulatory Class II, Panel Code 87.

2) Per 21 CFR as follows:

§888.3070 Thoracolumbar Pedicle Screw System

Product Codes NKB, KWQ
Regulatory Class II, Panel Code 87.

Primary Predicate: Medtronic KYPHON HV-R® Fenestrated Screw Cement and CD HORIZON® Fenestrated Screw Set (K152604)

Additional Predicates:
FORTRESS™ Radiopaque Bone Cement (K042168)
FORTRESS-Plus™ Radiopaque Bone Cement (K162618)
CONFIDENCE™ High Viscosity Spinal Cement, VIPER® and EXPEDIUM® Fenestrated Screw Systems (K160879)
REVLOK® Fenestrated Screw System (K110280)
Medtronic KYPHON Xpede Bone Cement and CD HORIZON Fenestrated Screw Set (K171938)

Purpose: The purpose of this submission is to request clearance for the CREO® Fenestrated Screw System and additional indications for use for the REVLOK® Fenestrated Screw System and FORTRESS™ and FORTRESS-Plus™ Radiopaque Bone Cements to be used for cement augmentation of the fenestrated screws in select advanced stage tumor patients. See Indications for Use.

Device Description:

1) ***FORTRESS™ Radiopaque Bone Cement***

FORTRESS™ Radiopaque Bone Cements (FORTRESS™, FORTRESS-Plus™) are radiopaque, self-curing PMMA bone cements. FORTRESS™ is provided as two sterile components, a liquid component and a powder component, which are mixed together prior to use to form the cement. The bone cement is intended for single use only.

2) ***CREO® Fenestrated Screw System***

CREO® Fenestrated Screw System consists of fenestrated monoaxial screws, uniplanar screws, polyaxial screws, dual outer diameter screws, reduction screws, rods and locking caps. Screws are available in a variety of sizes to accommodate individual patient anatomy. CREO® Fenestrated Screws mate with 4.75mm, 5.5mm, and 6.35mm diameter rods and connecting components from the CREO® Stabilization System. In addition, CREO Threaded screws and locking caps mate with 6.0mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws are intended for posterior use only. Staples are intended for anterior use only. Monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws to the rod.

CREO® Fenestrated Screws are composed of titanium alloy, cobalt chromium-molybdenum alloy, or stainless steel as specified in ASTM F136, F1537, F1295, F67 and F138. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants. CREO® Fenestrated Screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

REVLOK® Fenestrated Screw System

The REVLOK® Fenestrated Screw System consists of monoaxial screws, uniplanar screws, polyaxial screws, dual outer diameter screws, reduction screws, rods and locking caps. Screws and rods are available in a variety of sizes to accommodate individual patient anatomy. REVLOK® implants mate with 5.5mm diameter rods and REVLOK® 6.35 implants mate with 6.35mm diameter rods, and connecting components from the REVERE® Stabilization System. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Locking caps are used to connect the screws to the rod.

The rods are composed of titanium alloy, commercially pure titanium, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F67, F1537 and F138. All other REVLOK® implants are manufactured from titanium alloy or stainless steel, as specified in ASTM F136, F1295, F138, and F67. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be

connected to titanium or titanium alloy implants. The REVLOK® Fenestrated Screws are available with or without hydroxyapatite (HA) coating, as specified in ASTM F1185.

Indications for Use:

1) FORTRESS™ Radiopaque Bone Cements

FORTRESS™ Radiopaque Bone Cement (FORTRESS™ and FORTRESS-Plus™) is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with CREO® or REVLOK® Fenestrated Screw Systems for posterior fixation, FORTRESS™ Radiopaque Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. FORTRESS™ Radiopaque Bone Cement is limited to use at spinal levels where the structural integrity of the spine is not severely compromised.

2) CREO® Fenestrated Screw System

CREO® Fenestrated Screw System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the CREO® Fenestrated Screw System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the CREO® Fenestrated Screw System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

When used for posterior fixation in conjunction with FORTRESS™ or FORTRESS-Plus™ bone cement, the CREO® Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CREO® Fenestrated screws augmented with FORTRESS™ or FORTRESS-Plus™

bone cement are intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

REVLOK® Fenestrated Screw System

REVLOK® Fenestrated Screw System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, the REVLOK® Fenestrated Screw System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the REVLOK® Fenestrated Screw System is intended for anterolateral screw (with or without staple) fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e. scoliosis, kyphosis, and/or lordosis), fracture or dislocation of the thoracolumbar spine, pseudoarthrosis, tumor resection, and/or failed previous fusion. Levels of screw fixation are T8-L5.

When used for posterior fixation in conjunction with FORTRESS™ or FORTRESS-Plus™ bone cement, the REVLOK® Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. REVLOK® Fenestrated screws augmented with FORTRESS™ or FORTRESS-Plus™ bone cement are intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

Performance Data:

Clinical literature data and cadaveric testing was provided to support the substantial equivalence of the subject device. Mechanical testing (axial pull-out and torque removal testing of augmented screws) was conducted in accordance with ASTM F543 and the "Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s," May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:

1) ***FORTRESS™ Radiopaque Bone Cements***

The subject FORTRESS™ and FORTRESS-Plus™ devices have the same technological characteristics and indications as the corresponding predicate devices including design, intended use, material composition, and function. The main

differences between the subject and predicate cement are the methods in which the cement is delivered and that the subject cement is limited to patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

Subject FORTRESS bone cements and KYPHON HV-R and KYPHON Xpede Fenestrated Screw Cements are viscous PMMA bone cements intended to augment the fixation of screws in a posterior spinal system construct.

2) CREO® and REVLOK® Fenestrated Screw Systems

The subject CREO® and REVLOK® devices have the same technological characteristics and indications as the corresponding predicate devices including design, intended use, material composition, function, and range of sizes.

CREO® and REVLOK® are similar to Medtronic CD HORIZON Fenestrated screws as they are cannulated, manufactured from the same material, are similar in design, sizes and are intended to be used with spinal rods and connecting components. Subject and predicate screws are similar as they contain fenestrations which allow PMMA cement to flow in a controlled manner through the screw and into the targeted pedicle. The subject and predicate screws are also intended to provide pedicle fixation in patients diagnosed with spinal instability caused by select tumors - see indications for use.

Basis of Substantial Equivalence:

The CREO® and REVLOK® Fenestrated Screw Systems and FORTRESS™ Bone Cements have 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 and predicate devices.