510(k) Summary: CREO® Additional Implants and Navigated Instruments

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: August 30, 2018

Device Name: CREO® Stabilization System
Navigation Instruments
ExcelsiusGPS®

Classification: CREO® Additional Implants
Per 21 CFR as follows:
§888.3050 Spinal Interlaminal Fixation Orthosis
§888.3060 Spinal Intervertebral Body Fixation Orthosis
§888.3070 Pedicle Screw Spinal System
§888.3070 Spondylolisthesis Spinal Fixation Device System
§888.3070 Pedicle Screw Spinal System, Adolescent Idiopathic Scoliosis
Product Codes NKB, KWP
Regulatory Class: II, Panel Code: 87

Navigation Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instruments
Product Code OLO
Regulatory Class: II, Panel Code: 84

ExcelsiusGPS® Instruments
Per 21 CFR as follows:
§882.4560 Stereotaxic Instruments
Product Codes OLO, HAW
Regulatory Class: II, Panel Code: 87

Primary Predicate: CREO® Stabilization System (K124058)

Additional Predicates: CREO® Stabilization System
CREO® Stabilization (K143633, K180210, K181068)
DePuy Expedium Verse Spine System Fenestrated (K160879)

REVERE® Stabilization System (K061202, K091782, K122226)
REVERE® 4.5 Stabilization System (K113395)
CREO® and REVLOK® Fenestrated Screw System (K172269)

CREO® Navigation Instruments
Navigation Instruments (K153203, K180690)

CREO® ExcelsiusGPS® Instruments
ExcelsiusGPS® (K171651)

Purpose:
The purpose of this submission is to request clearance for additional CREO® implants, Navigation Instruments, and ExcelsiusGPS® Instruments.

Device Description:
CREO® Stabilization System
The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, fenestrated screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition.

CREO® implants are composed of titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138. Rods are also available in commercially pure titanium, as specified in ASTM F67. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. 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® Stabilization System include surgical instruments manufactured from stainless steel, as specified in ASTM F899.

CREO® Navigation Instruments
Navigation Instruments are nonsterile, reusable instruments that can be operated manually or under power using a power drill such as POWEREASE that are intended to be used with the Medtronic StealthStation® System.

CREO® ExcelsiusGPS® Instruments
ExcelsiusGPS® Instruments are nonsterile, reusable instruments that can be operated with the ExcelsiusGPS® robotic arm, or may be used for a freehand navigated surgical procedure.

Indications for Use

CREO® Stabilization System

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients. These devices are indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization 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 for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (4.5mm, 5.5mm, or 6.35mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE® or ELLIPSE® system package insert for instructions and indications of use.

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.

Globus Navigation Instruments are intended to be used during the preparation and placement of CREO® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid

anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

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™ and FORTRESS-Plus™ bone cements are for use at spinal levels where the structural integrity of the spine is not severely compromised.

CREO® Navigation Instruments

Globus Navigation Instruments are intended to be used during the preparation and placement of Globus screws (QUARTEX™, CREO®, REVERE®, REVOLVE®, ELLIPSE®, PROTEX®-CT, and SI-LOK®) during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

CREO® ExcelsiusGPS® Instruments

The ExcelsiusGPS® is intended for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

Performance Data:

Mechanical testing (static and dynamic compression and static torsion) was conducted in accordance with ASTM F1717 and the “Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s,” May 3, 2004 to demonstrate substantial equivalence of the subject CREO implants to the predicate devices. Bacterial endotoxin testing (BET) was conducted in accordance with ANSI/AAMI ST-72:2011.

Technological Characteristics:
Subject CREO® implants, Navigation instruments, and ExcelsiusGPS® instruments have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Basis of Substantial Equivalence:
Subject CREO® implants and instruments are similar to the predicate device with respect to technological characteristics, performance, design, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.