510(k) Summary: ExcelsiusGPS® High Speed Drill 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: April 3, 2019

Device Name: ExcelsiusGPS®

Common Name: Orthopedic Stereotaxic Instrument

Classification: Per 21 CFR as follows:
§882.4560 Stereotaxic instrument
Product Code(s): OLO
Regulatory Class: II, Panel Code: 84

Primary Predicate: ExcelsiusGPS® (K171651)

Additional Predicate: AQrate™ Robotic Assistance System (K182000)

Purpose:
The purpose of this submission is to request clearance of the High Speed Drill Instruments for use with ExcelsiusGPS®.

Device Description:
The High Speed Drill Instruments consist of an array, array sleeves, a drill guard, and drill bits. These instruments are provided non-sterile, except for the drill bits which are provided sterile or non-sterile. These instruments are intended to be used with ExcelsiusGPS® and are manufactured from stainless steel, per ASTM F899, and PEEK.

Indications for Use:
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.

Technological Characteristics:
Subject ExcelsiusGPS® High Speed Drill Instruments have the same technological characteristics as predicate instruments including design, intended use, material composition, function, and range of sizes.

Performance Testing:
Verification and Validation testing and comparison to the predicate demonstrate that the ExcelsiusGPS® High Speed Drill Instruments can be used in accordance with its indications.

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.

Basis of Substantial Equivalence:
The ExcelsiusGPS® High Speed Drill Instruments 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.