510(k) Summary: AERIAL™ Interspinous Fixation

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

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Device Name: AERIAL™ Interspinous Fixation

Common Name: Spinal interlaminal fixation orthosis

Classification: Per 21 CFR as follows:
§888.3050 Spinal interlaminal fixation orthosis
Product Code: PEK
Regulatory Class: II

Primary Predicate: SP-Fix® Spinous Process Fixation System (K180156)

Additional Predicates: SP-Fix® Spinous Process Fixation System (K102195, K132191)
Alphatec BridgePoint (K103205)
CD HORIZON SPIRE (K163301)

Purpose:
The purpose of this submission is to request clearance of AERIAL™ Interspinous Fixation.

Device Description:
AERIAL™ Interspinous Fixation is an expandable non-cervical interspinous fixation device used to provide supplemental stabilization of spinal segments to support fusion. The components are available in a range of sizes to fit the anatomical needs of a variety of patients.

Indications for Use:
The AERIAL™ Interspinous Fixation is a posterior non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. AERIAL™ is intended for use with allograft or autograft bone and is not intended for stand-alone use.

Performance Data:
Testing was conducted to demonstrate performance in axial compression, plate dissociation, offset torsion, and tension.

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:
Subject AERIAL™ 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:
AERIAL™ Interspinous Fixation has 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.