



October 23, 2019

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

Re: K192314

Trade/Device Name: RESONATE™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 23, 2019
Received: August 26, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

<https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

(Ronald Jean) Vacant
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192314

Device Name

RESONATE™ Anterior Cervical Plate System

Indications for Use (Describe)

The RESONATE™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

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.

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510(k) Summary: RESONATE™ Anterior Cervical Plate System

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 23, 2019

Device Name: RESONATE™ Anterior Cervical Plate System

Common Name: Anterior Cervical Plate System

Classification: Per 21 CFR as follows:
§888.3060 Spinal Intervertebral Body Fixation Orthosis
Product Code: KWQ
Regulatory Class: II, Panel Code: 87

Primary Predicate: XTEND® Anterior Cervical Plate System (K092146)

Additional Predicates: ASSURE® Anterior Cervical Plate System (K040721)
UNIFY® Dynamic Anterior Cervical Plate System (K121049)
Medtronic ZEVO Anterior Cervical Plate System (K141632)

Purpose:

The purpose of this submission is to request clearance for the RESONATE™ Anterior Cervical Plate System.

Device Description:

The RESONATE™ Anterior Cervical Plate System consists of cervical plates offered in various sizes to accommodate a variety of spinal levels based on surgical need and anatomic requirements. The plate attaches to the anterior portion of the vertebral body of the cervical spine. The plates can be used with fixed angle or variable angle screws. RESONATE™ implants are manufactured from titanium alloy and Nitinol.

Indications for Use:

The RESONATE™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-T1) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including

fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

Technological Characteristics:

RESONATE™ implants have the same technological characteristics as the predicate devices including design, intended use, material composition, function, and range of sizes.

Performance Data:

Mechanical testing (static and dynamic compression bending, 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. Performance data demonstrate substantial equivalence to the predicate device. Corrosion testing was also conducted on the RESONATE™ plates in accordance with ASTM F2129.

Basis of Substantial Equivalence:

The RESONATE™ Anterior Cervical Plate System has been found to be substantially equivalent to the predicates with respect to technological characteristics, design, materials, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices.