August 5, 2020

SeaSpine Orthopedics Corporation
Alicia McArthur
Specialist, Regulatory Affairs
5770 Armada Drive
Carlsbad, California 92008

Re: K201240
Trade/Device Name: Mariner Cap System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: May 6, 2020
Received: May 8, 2020

Dear Alicia McArthur:

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,

Colin O'Neill, M.B.E.
Acting 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

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)*
K201240

Device Name
Mariner Cap System

Indications for Use *(Describe)*
The Mariner Cap System is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Mariner Cap System shall be used in conjunction with the SeaSpine Mariner Pedicle Screw System whenever "wiring" may help secure the attachment of other implants.

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.

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510(k) Summary

Contact Details

Applicant Name: SeaSpine® Orthopedics Corporation

Address: 5770 Armada Drive, Carlsbad, CA 92008
Phone number: (760) 216-5176
Fax number: (760) 683-6874

Primary Contact: Alicia McArthur, Regulatory Affairs Specialist
Secondary Contact: Jesse Albright, Regulatory Affairs Specialist

Date Prepared: July 29, 2020

Device Name

Trade Name: Mariner Cap System

Common Name: Bone Fixation Cerclage, Sublaminar

Classification Name: Bone Fixation Cerclage (21 CFR 888.3010)

Class: II

Product Code: OWI

Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
PRIMARY PREDICATE Device			
K182771	NKB, OWI	ISS-JAZZ Screw System and JAZZ CAP SP	Implanet
REFERENCE Device			
K173882	NKB	Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation

Device Description

The Mariner Cap is composed of three components: the Mariner Cap SP Connector, the Mariner Cap SP Locking Base, and the Locking Insert. The cap is designed to mate with the Mariner Pedicle Screw System screws. The Mariner Cap is added to the proximal end of the Mariner Screw and provides for an alternate method to attach the JAZZ Band and JAZZ Passer Band to skeletal structures as compared to the current method using a JAZZ connector (K171881).

Indications for Use

The Mariner Cap System is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.

The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Mariner Cap System shall be used in conjunction with the SeaSpine Mariner Pedicle Screw System whenever "wiring" may help secure the attachment of other implants.

Summary of Technological Characteristics

The Mariner Cap System provides an alternate way to allow for braid attachment to the spine. The Mariner Cap System when used with the Mariner Pedicle Screw System, provides a more efficient, lower profile method of adding the braid attachment to the fixation construct by attaching the JAZZ Passer Band to the Mariner Cap designed to attach to the proximal end of the screw. The locking mechanism used for the braid component in the Mariner Cap is identical to that already cleared in the JAZZ CAP (K182771).

The Mariner Cap System was shown to be substantially equivalent and have equivalent technological characteristics to the cited predicate and reference device in regard to components, device description, intended use/indications for use, technological characteristics (i.e., operating principle, design, materials, sterility, manufacturing, etc.) and performance (i.e., mechanical testing).

Non-Clinical Testing

The Mariner Cap System demonstrated similar performance to the predicate system through dynamic compression testing with reference to ASTM 1717 and static compression testing.

Clinical Testing

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusions

The submitted data demonstrates that the Mariner Cap System has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.