May 17, 2024

EffortMed, LLC
% J.D. Webb
President
The OrthoMedix Group, Inc.
4313 W. 3800 S.
West Haven, Utah 84401

Re: K240935
Trade/Device Name: Arenal 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: April 3, 2024
Received: April 5, 2024

Dear J.D. Webb:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Colin O'Neill, MBE
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240935

Device Name

Arenal Anterior Cervical Plate System

Indications for Use *(Describe)*

The ARENAL Anterior Cervical Plate System is intended for fixation and temporary stabilization of the anterior cervical spine (C2-T1) during the development of cervical spine fusions in patients with 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
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Spondylolisthesis
- 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.

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510(k) #: K240935

510(k) Summary

Prepared on: 2024-04-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	EffortMed, LLC
Applicant Address	4766 NW 91st Way Coral Springs FL 33067 United States
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Applicant Contact	Mr. Steven Brown
Applicant Contact Email	sbrown@effortmed.com
Correspondent Name	The OrthoMedix Group, Inc.
Correspondent Address	4313 W. 3800 S. West Haven UT 84401 United States
Correspondent Contact Telephone	512-590-5810
Correspondent Contact	Mr. J.D. Webb
Correspondent Contact Email	jdwebb@orthomedix.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Arenal Anterior Cervical Plate System
Common Name	Spinal intervertebral body fixation orthosis
Classification Name	Appliance, Fixation, Spinal Intervertebral Body
Regulation Number	888.3060
Product Code(s)	KWQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K162638	CETRA™ Anterior Cervical Plate System	KWQ
K211718	Venus Cervical Plate System	KWQ

Device Description Summary

21 CFR 807.92(a)(4)

The ARENAL Anterior Cervical Plate System is intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping or self-drilling bone screws using an anterior approach. Plates are available in a variety of lengths, addressing multiple levels of fixation.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ARENAL Anterior Cervical Plate System is intended for fixation and temporary stabilization of the anterior cervical spine (C2-T1) during the development of cervical spine fusions in patients with 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
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Spondylolisthesis
- Spinal stenosis

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Arenal Anterior Cervical Plate System has the same Indications for Use as the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

Indications for Use: no difference
Materials: no difference
Design/geometry: similar
Dimensions: similar
Operating Principle: no difference
Sterility: no difference
There are no substantial differences between the Arenal Anterior Cervical Plate System and

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following tests were performed in determining substantial equivalence of the ARENAL Anterior Cervical Plate:

-Static compression per ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
*Static Compression Bending Yield was in excess of the acceptance criteria listed in FDA Spinal Plating Systems guidance document.
*Static Compression Bending Stiffness was in excess of the acceptance criteria listed in FDA Spinal Plating Systems guidance document.

-Dynamic compression per ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
*Dynamic Compression Bending Runout Load @ 5M cycles was in excess of the acceptance criteria listed in FDA Spinal Plating Systems guidance document.

-Static torsion per ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
*Static Torsion Yield was in excess of the acceptance criteria listed in FDA Spinal Plating Systems guidance document.
*Static Torsion Stiffness was in excess of the acceptance criteria listed in FDA Spinal Plating Systems guidance document.

Not Applicable

The Arenal Anterior Cervical Plate System is substantially equivalent to the legally marketed device identified above.