January 15, 2025

EffortMed, LLC
℅ J.D. Webb
President
The OrthoMedix Group, Inc.
4313 West 3800 South
West Haven, Utah 84401

Re: K243946
Trade/Device Name: EffortMed Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: December 18, 2024
Received: December 20, 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jisun Yoo -S

for Colin O'Neill, M.B.E.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243946

Device Name
EffortMed Spinal Fixation System

Indications for Use *(Describe)*
EffortMed Spinal Fixation System is intended for use in the noncervical spine. When used as a posterior, noncervical pedicle and non- pedicle fixation system, the EffortMed Spinal Fixation System is intended to provide additional support during fusion using autograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

• Degenerative disc disease (DDD) (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)
• Spinal stenosis
• Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
• Tumor
• Pseudoarthrosis; and failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EffortMed Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EffortMed Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/ spondylolysis,fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The EffortMed Spinal Fixation System is intended to be used with autograft and/or allograft.

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.

510(k) #: K243946

510(k) Summary

Prepared on: 2024-12-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	EffortMed, LLC
Applicant Address	4766 NW 91st Way Coral Springs FL 33067 United States
Applicant Contact Telephone	917-566-3479
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	EffortMed Spinal Fixation System
Common Name	Thoracolumbosacral pedicle screw system
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3070
Product Code(s)	NKB, KWP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241657	Msfx MIKRON Spinal Fixation System	NKB
K241892	Cortera™ Spinal Fixation System	NKB

Device Description Summary

21 CFR 807.92(a)(4)

EffortMed Spinal Fixation System is a top-loading, multiple component, posterior spinal fixation system consisting of polyaxial pedicle screws, monoaxial pedicle screws, cannulated and spondylolisthesis screws, rods (Straight and curved) , connectors , hooks and setscrews. It allows surgeons and functions to build a spinal implant construction to stabilize and promote spinal fusion. The System components are supplied non-sterile, for single use and fabricated from titanium alloy (Ti6Al4V-ELI) that conforms to ASTM F136. Various sizes of these components are available.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

EffortMed Spinal Fixation System is intended for use in the noncervical spine. When used as a posterior, noncervical pedicle and non-pedicle fixation system, the EffortMed Spinal Fixation System is intended to provide additional support during fusion using autograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- Degenerative disc disease (DDD) (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)
- Spinal stenosis
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis; and failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the EffortMed Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the EffortMed Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis,fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The EffortMed Spinal Fixation System is intended to be used with autograft and/or allograft.

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

The subject system has the same indications for use as the Msfx system, except the subject system includes pediatric use. The subject system has the same indications for use as the Cortera system.

Technological Comparison 21 CFR 807.92(a)(6)

Indications for Use: no difference
Materials: no difference
Operating Principle: no difference
Design/geometry: no difference
Dimensions: no difference
Material: no difference
Sterility: no difference
There are no differences between the EffortMed Spinal Fixation System and the predicates

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

The following tests were performed in determining substantial equivalence of the EffortMed Spinal Fixation System:

-ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

-ASTM F1798: Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
  -Axial gripping capacity
  -Axial torque gripping capacity
  -Flexion-extension moment

-ASTM F543: Test Methods for Metallic Medical Bone Screws
  -Annex A3-Test Method for Determining the Axial Pullout Strength of Medical Bone Screws.
  -Determining the comparable shear failure force following the equation of Chapman, J.R., et al

-Tulip-dissociation testing on the worst-case bottom-loading screw construct at neutral and maximum screw angulations to evaluate the interconnection strength

Clinical data: Not applicable

The EffortMed Spinal Fixation System is substantially equivalent to the legally marketed predicate device identified above.