November 21, 2025

EffortMed LLC
% J.D. Webb
President
The OrthoMedix Group, Inc.
4314 W. 3800 S.
West Haven, Utah 84404

Re: K252686
Trade/Device Name: EffortMed PEEK Cages & Corpectomy Cages
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, OVE, MAX, MQP, PLR
Dated: September 19, 2025
Received: September 19, 2025

Dear Mr. 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,

KATHERINE D. KAVLOCK -S

for
Brent Showalter, Ph.D.
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

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K252686 |

Please provide the device trade name(s).

EffortMed PEEK Cages & Corpectomy Cages

Please provide your Indications for Use below.

EFFORTMED CERVICAL PEEK CAGES are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. CERVICAL PEEK CAGES facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autograft/autologous bone graft. Patients should have received at least six (6) months of prior non-operative treatment. EFFORTMED CERVICAL PEEK CAGES are to be used with supplemental fixation.

The EFFORTMED LUMBAR PEEK CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

The EFFORTMED ORIZABA CERVICAL CORPECTOMY CAGE is intended for use in skeletally mature patients in the cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The EFFORTMED COTOPAXI LUMBAR CORPECTOMY CAGE is intended for use in skeletally mature patients in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The ORIZABA and COTOPAXI CORPECTOMY CAGES are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon’s discretion.

ORIZABA and COTOPAXI CORPECTOMY CAGES are intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material is optional.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252686

# 510(k) Summary

Prepared on: 2025-09-18

## 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 | sbbiomed@hotmail.com |
| Correspondent Name | The OrthoMedix Group, Inc. |
| Correspondent Address | 4314 W. 3800 S. West Haven UT 84404 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 PEEK Cages & Corpectomy Cages |
| Common Name | Intervertebral Fusion Device with Bone Graft, Cervical; Intervertebral Fusion Device with Bone Graft, Lumbar; Spinal vertebral body replacement device; Spinal vertebral body replacement device – Cervical |
| Classification Name | Intervertebral body fusion device; Spinal intervertebral body fixation orthosis |
| Regulation Number | 21 CFR 888.3080; 21 CFR 888.3060 |
| Product Code(s) | ODP, OVE, MAX, MQP, PLR |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K240893 | ARTFX MEDICAL Cervical PEEK Cages | ODP |
| K240889 | ARTFX Lumbar PEEK Cages | MAX |
| K211892 | ARTFX CORPECTOMY CAGES | MQP |
| K211892 | ARTFX CORPECTOMY CAGES | PLR |

## Device Description Summary

21 CFR 807.92(a)(4)

The EffortMed spinal interbody cage system includes cervical intervertebral body fusion (IBFD), transforaminal lumbar interbody fusion (TLIF), and posterior lateral interbody fusion (PLIF) devices. The cervical cage models are the EffortMed Pacaya Cervical PEEK Cage and Masaya Augmented Cervical PEEK cage. The lumbar cage models are the EffortMed TLIF PEEK Cage, Effortmed TLIF PEEK Cage 4° Angled, Effortmed PLIF PEEK Cage, EffortMed PLIF PEEK Cage 5° Angled, and EffortMed Expandable PLIF PEEK Cage. The system was designed to restore height and lordotic angle in the spine. The main role of the cages is to help maintain the cleared disc space stable and intact, until a healthy bony fusion occurs between the adjoining vertebrae. To help achieve this, the inner chamber of the cage body is filled with bone graft before implantation.

The system also includes cervical and corpectomy cages (identified as used in cervical spine (C2-T1) and in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to, tumors, fractures, and infections. The corpectomy cage models are the EffortMed Orizaba Cervical Corpectomy cage and EffortMed Cotopaxi Lumbar Corpectomy cage.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

EFFORTMED CERVICAL PEEK CAGES are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. CERVICAL PEEK CAGES facilitate intervertebral body fusion in the cervical spine and are placed via the anterior approach and packed with autograft/autologous bone graft. Patients should have received at least six (6) months of prior non-operative treatment. EFFORTMED CERVICAL PEEK CAGES are to be used with supplemental fixation.

The EFFORTMED LUMBAR PEEK CAGES are indicated for intervertebral body fusion at one or two contiguous levels in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) of lumbar spine with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).
Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received at least six (6) months of prior non-operative treatment. The devices are designed to be used with supplemental fixation and autograft/autologous bone graft to facilitate fusion for each spinal region.

The EFFORTMED ORIZABA CERVICAL CORPECTOMY CAGE is intended for use in skeletally mature patients in the cervical spine (C2-T1) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The EFFORTMED COTOPAXI LUMBAR CORPECTOMY CAGE is intended for use in skeletally mature patients in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The ORIZABA and COTOPAXI CORPECTOMY CAGES are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

ORIZABA and COTOPAXI CORPECTOMY CAGES are intended to be used with supplemental spinal fixation systems cleared for use in the cervical, thoracic, and/or lumbar spine. The use of bone grafting material is optional.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the EffortMed PEEK Cages & Corpectomy Cages and the predicate devices are the same.

## Technological Comparison

21 CFR 807.92(a)(6)

Indications for Use: no difference
Design: no difference
Sizes: no difference
Material: no difference
Principles off operation: no difference

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The EffortMed PEEK Cages and Corpectomy Cages are exactly the same geometry and material as the predicate device. Therefore, the non-clinical testing performed in support of the predicate device is applicable to the EffortMed devices.

Clinical Testing - Not applicable

The EffortMed PEEK Cages and Corpectomy Cages are substantially equivalent to the legally marketed predicate device identified above.