April 1, 2026

Orthomod, LLC
David Kirschman, MD
CEO
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K242303
Trade/Device Name: MOD-C
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: September 8, 2025
Received: September 9, 2025

Dear Dr. Kirschman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Brent Showalter -S

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

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)*

K242303

Device Name

MOD-C

Indications for Use *(Describe)*

The Orthomod MOD-C™ Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The MOD-C device is to be used with supplemental fixation, such as a cervical plate system. The MOD-C device is designed for use with autogenous and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion and is to be implanted via an anterior approach.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Orthomod, LLC
MOD-C
August 2, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Orthomod, LLC 350 Fame Road Dayton, OH, 45449 Telephone +1 513-817-4066
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DEVICE NAME AND CLASSIFICATION

Trade/Device Name	MOD-C
Common Name	Cervical interbody fusion device
Regulation Number	21 CFR 888.3080
Regulation Name	Intervertebral body fusion device
Regulatory Class	Class II
Product Code	ODP
Classification Panel	Orthopedic
Reviewing Office	Office of Health Technology 6 (Orthopedic Devices)
Reviewing Division	Division of Spinal Devices

PREDICATE DEVICE INFORMATION

K171075,	Calix-C™ Cervical Interbody Spacer, X-Spine Systems, Inc.
K181115,	CxHA™ PEEK Cervical IBF System, Innovasis, Inc.
K142264,	Valeo™ Spacer System, Valeo™ II Interbody Fusion Device System, AMEDICA® Corporation
K111264	CORNERSTONE® PSR Cervical Fusion System, Medtronic Sofamor Danek USA

The primary predicate device is K171075. K181115, K142264, and K111264 are additional predicate devices.

The primary and additional predicate devices support substantial equivalence, including indications for use, designs, materials, and mechanical testing performance.

INDICATIONS FOR USE STATEMENT

The Orthomod MOD-C™ Cervical IBF System is indicated for cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The MOD-C device is to be used with supplemental fixation, such as a cervical plate system. The MOD-C device is intended to be used with autogenous and/or allogeneic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion and is to be implanted via an anterior approach.

SUBJECT DEVICE DESCRIPTION

MOD-C implants have a rounded, rectangular footprint with overall dimensions of 16 mm (medial-lateral) x 12 mm (anterior-posterior), with heights ranging from 5 mm to 12 mm in 1 mm increments. The implants are provided in each height with endplates that are parallel or with endplates having 7° of lordosis. To allow for placement of autogenous bone graft, MOD-C implants have two hollow chambers, open to the superior and inferior surfaces, each with a rounded rectangular shape (footprint).

MOD-C implants are manufactured from a composite of an acrylic polymer and synthetic beta-tricalcium phosphate/ hydroxyapatite (ß-TCP/HA). The acrylic conforms to ASTM F3087, the synthetic ß-TCP conforms to ASTM F1088, and the HA conforms to ASTM F1185. MOD-C implants are provided sterile by gamma irradiation for single patient use.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included:

- sterilization gamma irradiation sterilization validation to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin testing including Limulus amebocyte lysate (LAL) test according to USP <85> to demonstrate that all sterile product meets a limit of < 20 EU/device;
- reprocessing validation for the device-specific instruments according to AAMI TIR12 and AAMI TIR30;
- moist heat sterilization for the device-specific instruments, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79;
- shelf life testing of samples after accelerated aging to the equivalent of one (1) year of real time aging according to ASTM F1980, with testing of the packaging sterile barrier and analysis of the implant devices;
- biocompatibility testing according to ISO 10993-5, ISO 10993-10, ISO 10993-23, ISO 10993-11, ISO 10993-3, ISO 10993-18, and a toxicological risk assessment according to ISO 10993-17;
- static and dynamic axial compression, static and dynamic compression shear, and static and dynamic torsion per ASTM F2077, subsidence per ASTM F2267, and expulsion testing; and
- animal studies using a standardized osseointegration model in cortical and cancellous sites comparing the subject device material to PEEK and titanium alloy implants after time periods of 3, 6, 12, and 26 weeks.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The Indications for Use Statement for the subject device is substantially equivalent to that of the predicate devices. All are indicated for single-level fusion in the cervical spine from C2 to T1 for patients with degenerative disc disease, who have had an adequate duration (6 weeks) of non-operative treatment prior to treatment with the device. The subject device and predicate devices all are indicated for use with supplemental cervical fixation. Slight differences in the specific language among the Indications for Use Statements do not change the intended use or impact the substantial equivalence of the Indications for Use Statements. The additional predicate device K142264 has additional indications for use in the lumbar spine, which does not affect the indications for use in the cervical spine.

The design and overall range of dimensions of subject device implants are similar to those of the predicate devices. The superior and inferior surfaces of subject device and predicate devices are serrated (transverse ridges or teeth) and

designed to help stabilize the device and resist unwanted intraoperative and postoperative migration. Similarly, the designs of the subject device and predicate devices include a hollow architecture with superior and inferior openings that together enable placement of autogenous bone graft for the purpose of achieving a solid fusion mass with the adjacent vertebral body endplates. The range of overall dimensions (medial-lateral width, anterior-posterior depth) and heights of the subject device are substantially equivalent to those of the predicate devices. The footprint (implant cross-sectional area), volume available for bone graft, and lordotic angles of the subject device are substantially equivalent to the primary predicate device.

Mechanical testing performed according to ASTM F2077, ASTM F2266, and expulsion testing demonstrated the subject device to be substantially equivalent to the primary predicate device or to published literature.

CONCLUSION

Any differences in the technological characteristics between the subject device and predicate devices do not raise different questions of safety or effectiveness. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, the subject device has the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate similar materials, and
- have similar packaging and are sterilized using the same materials and processes.