



July 8, 2026

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

Re: K254130

Trade/Device Name: C.A. Medical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: June 8, 2026
Received: June 9, 2026

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 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

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.

K254130

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Please provide the device trade name(s).

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C.A. Medical Interbody Fusion System

Please provide your Indications for Use below.

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When used as a cervical intervertebral body fusion device, the C.A. Medical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

When used as a lumbar intervertebral body fusion device, the C.A. Medical Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	C.A. Medical, LLC
Applicant Address	431 East State Highway 114 Suite 160 Southlake TX 76092 United States
Applicant Contact Telephone	877-396-3442
Applicant Contact	Mr. Harold Childs
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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	C.A. Medical Interbody Fusion System
Common Name	Intervertebral body fusion device With Bone Graft, Cervical Intervertebral body fusion device With Bone Graft, Lumbar
Classification Name	Intervertebral body fusion device
Regulation Number	888.3080
Product Code(s)	ODP, MAX

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K110659	Medical Concepts Interbody Fusion System	MAX
K251335	Tera Lumbar Interbody Fusion System	MAX
K251735	Stabilis SA Cervical Stand-Alone System	ODP

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The proposed C.A. Medical Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

- Cervical interbody fusion device(s), which may be implanted as a single device via an anterior approach, and
- Lumbar interbody fusion device(s), which may be implanted
 - bi-laterally via a posterior (PLIF) approach

- as a single device via a transforaminal (TLIF) approach; or
- as a single device via an anterior/anterolateral (ALIF).

The implants are offered in configurations manufactured from PEEK Optima HA with tantalum radiographic markers or additively manufactured from titanium alloy Ti-6Al-4V ELI per ASTM F3001. Implants are supplied sterile.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

When used as a cervical intervertebral body fusion device, the C.A. Medical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

When used as a lumbar intervertebral body fusion device, the C.A. Medical Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The C.A. Medical Interbody Fusion System has the same indications for use as the Medical Concepts Interbody Fusion System.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Indications for use: Same as Medical Concepts Cervical Interbody Fusion System (K110659)

Principle of Operation: Same as Medical Concepts Cervical Interbody Fusion System (K110659)

Design: Same as Medical Concepts Cervical Interbody Fusion System (K110659)

Sizes: Same as Medical Concepts Cervical Interbody Fusion System (K110659)

Material: Same as Medical Concepts Cervical Interbody Fusion System (K110659) and Acuity Stabilis SA Cervical Stand-Alone System (K251735) and Tera Lumbar Interbody Fusion System (K251335)

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Static and dynamic compression testing per ASTM F2077 and dynamic torsion and compression shear testing per ASTM F2077 were conducted.

Based on the overall technology characteristics and mechanical performance data in this submission, the C.A. Medical Interbody Fusion System is determined to be substantially equivalent to the predicate devices.