April 22, 2026

Carlsmed, Inc.
Jesse Albright
Sr. Manager, Regulatory Affairs
1800 Aston Ave. Suite 100
Carlsbad, California 92008

Re: K260570
Trade/Device Name: corra™ cervical plating system
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 6, 2026
Received: March 6, 2026

Dear Jesse Albright:

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,

MAZIAR SHAH-MOHAMMADI -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.	K260570

Please provide the device trade name(s).

corra™ cervical plating system

Please provide your Indications for Use below.

The corra™ cervical plating system is intended for anterior cervical fixation (C2-T1) for the following indications:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudoarthrosis, and
- Failed previous 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)

510(k) Summary

Contact Details

Applicant: Carlsmed, Inc.
Address: 1800 Aston Ave Ste 100
Carlsbad, CA 92008
Phone number: (760) 766-1923

Contact person: Jesse Albright
Sr. Manager, Regulatory Affairs
jalbright@carlsmed.com

Date prepared: April 10, 2026

Device Name

Trade name: corra™ cervical plating system

Common name: Appliance, Fixation, Spinal Intervertebral Body

Classification name: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)

Class: II

Product code: KWQ

Legally Marketed Predicate/Reference Devices

510(k) Number	Product Code	Trade Name	Manufacturer
Primary Predicate Device			
K252611	KWQ	aprevo® cervical plating system	Carlsmed, Inc.
Additional Reference Device(s)			
K252894	OVE, ODP	aprevo® cervical interbody system	Carlsmed, Inc.

Device Description

The corra™ cervical plating system, which is comprised of the corra™ cervical segmental plating system and the corra™ cervical multilevel plating system configurations, is intended for anterior fixation of the cervical spine. The system consists of a variety of patient-specific segmental and multilevel plates that are additively manufactured from titanium alloy (Ti-4Al-6V ELI) per ASTM F3001 as well as a range of screws manufactured from titanium alloy (Ti-4Al-6V ELI) per ASTM F136. The associated system instruments, which facilitate the placement, adjustment, and

removal, if necessary, of the implants, are manufactured from medical-grade materials, such as stainless steels and plastics.

Indications for Use

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- Tumor,
- Pseudoarthrosis, and
- Failed previous fusion.

Summary of Technological Characteristics

The corra™ cervical plating system technological characteristics are substantially equivalent to the cited predicate device. The equivalence determination was based on comparison of intended use/indications for use, technological characteristics (e.g., operating principle, design, components, materials, biocompatibility, manufacturing, labeling, sterility, etc.), and non-clinical testing.

Non-Clinical Testing

Dynamic compression shear testing was performed in accordance with ASTM F2077 to evaluate the updated design feature of the corra™ cervical plating system.

Clinical Testing

Not applicable. The determination of substantial equivalence is not based on an assessment of clinical performance data.

Conclusion

The submitted data demonstrates that the subject corra™ cervical plating system is substantially equivalent to the cited legally marketed predicate device.