January 8, 2026

Intelivation Technologies
Amit Sinha
President
500 S. Gravers Rd.
Suite 200
Plymouth Meeting, Pennsylvania 19462

Re: K252711
Trade/Device Name: Advantage-C™ Ti3D Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 17, 2025
Received: December 17, 2025

Dear Amit Sinha:

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,

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.

510(k) Number *(if known)*
K252711

Device Name
Advantage-C Ti 3D Cervical Interbody Fusion Device

Indications for Use *(Describe)*
The Advantage-C Ti 3D Cervical Interbody Fusion Device is a cervical Interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with/without radicular symptoms at one level from C2-T1. DDD is defined as diagnostic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Advantage-C Ti 3D Cervical Interbody Fusion Device is intended for use with supplemental fixation systems and with autogenous bone graft. Advantage-C Ti 3D Cervical Interbody Fusion Device is supplied non-sterile and is intended for one-time use.

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

Intelivation Technologies' Advantage-C™ Ti3D Cervical Interbody Fusion Device

I. Submitter

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Date Prepared: August 27, 2025

II. Subject Device

Trade Name:	Advantage-C Ti3D Cervical Interbody Fusion Device
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with Bone Graft, Cervical
Regulation Number:	21 CFR 888.3080
Regulatory Class:	Class II
Product Code:	ODP

III. Purpose of 510(k): New Interbody Device

IV. Predicate Devices

- *Primary: Advantage-PEEK Cervical Interbody Fusion Device* (K211501)
- *Additional: Zavation Ti3Z Cervical Interbody Fusion Device* (K191354)

V. Device Description

The Advantage-C Ti3D Cervical Interbody Fusion Device is a non-sterile, single-use implant made of titanium alloy (Ti-6Al-4V ELI, ASTM F3001-14). The device is offered in various sizes, footprints, heights, and lordotic angles to accommodate patient anatomy and surgical preference.

The device features a central graft window intended to be packed with autogenous bone graft to facilitate fusion. It is designed for use with cleared supplemental fixation systems. Insertion is performed using dedicated instruments, including a two-part inserter system designed for secure alignment and accurate placement.

Intended Use / Indications for Use

The Advantage-C Ti3D Cervical Interbody Fusion Device is intended for intervertebral body fusion of the cervical spine (C2–T1) in skeletally mature patients with degenerative disc disease (DDD) at one level with accompanying radicular symptoms. DDD is defined as discogenic pain with degeneration confirmed by history and radiographic studies.

The device is intended for use with autogenous bone graft and must be used with supplemental fixation systems cleared for use in the cervical spine.

Technological Characteristics

The Advantage-C Ti3D is implants are additively manufactured from medical grade Titanium Ti64ELI.

Comparison of Technological Characteristics with the Predicate Devices: (Substantial Equivalence)

The Advantage-C Ti shares the same Indications for Use as the primary predicate device, Advantage-C PEEK (K211501). Its material composition and manufacturing methods are consistent with the additional predicate device, Ti3Z Cervical Interbody System by Zavation (K191354). The subject device introduces no new technological characteristics that raise new questions of safety or effectiveness. Thus, the subject device is identical to predicate devices.

Performance Data

Non-clinical testing was conducted in accordance with FDA Guidance and relevant ASTM standards, including:

- Static and dynamic axial compression (ASTM F2077)
- Static and Dynamic Torsion (ASTM F2077)

- Static Subsidence (ASTM F2267
- Static Expulsion

All testing demonstrated that the Advantage-C™ Ti3D device meets the performance requirements for its intended use and is substantially equivalent to the predicate devices.

Clinical Data:
Clinical studies were not required for this submission.

7. Conclusion

The Advantage-C™ Ti3D Cervical Interbody Fusion Device is substantially equivalent to the cited predicate devices in terms of intended use, technological characteristics, and performance. The data provided supports a finding of substantial equivalence under Section 510(k) of the FD&C Act.