August 24, 2021

Intelivation, LLC
Jack Griffis
Regulatory Affairs
70 Gruber Lane
Saint Simons Island, Georgia 31522

Re: K211501
Trade/Device Name: *Advantage-C* PEEK Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: July 23, 2021
Received: July 26, 2021

Dear Jack Griffis:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211501

Device Name
Advantage-C PEEK Cervical Interbody Fusion Device

Indications for Use *(Describe)*
The Advantage-C PEEK 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 discogenic 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 PEEK Cervical Interbody Fusion Device is intended for use with supplemental fixation systems and with autogenous bone graft.. The Advantage-C PEEK Cervical Interbody Fusion Device is supplied 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

INTELIVATION TECHNOLOGIES

510(k) Summary

510(k) Number: K211501

Date Submitted: July 23rd, 2021

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
Intelivation, LLC
70 Gruber Lane
Saint Simons Island, GA 31522
912-434-2780

B. Company Contact:
Jack Griffis
Regulatory Affairs
(404) 583-6889 (direct)
jackgriffisiii@gmail.com

C. Device Information:
Trade Name: *Advantage-C* PEEK Cervical Interbody Fusion Device
Common Name: Intervertebral Fusion Device, Cervical

D. Classification: Intervertebral Fusion Device
21 CFR §888.3080 (ODP)
Class II

E. Predicate Device:
Zimmer-Biomet Vista®-S PEEK Cervical Cage System, K111983 (Primary)
Zimmer-Biomet Vista®-S PEEK Cervical Cage System, K133784

F. Reference Predicate Device:
Zavation Interbody Fusion System (IBF), K162206

G. Physical Description:
The proposed Intelivation Advantage-C Cervical Interbody Fusion Device is a sterile, single use implant grade polyetheretherketone (PEEK; ASTM F2026) device and Tantalum (ASTM F560), available in varied footprints and heights, designed for supplemental stabilization of the cervical spinal column in anterior cervical discectomy and fusion (ACDF) procedures. The device is intended for spinal fusion procedures at one level in skeletally mature patients with degenerative disc disease (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. The implant should be used with supplemental spinal fixation systems and with autogenous bone graft.

H. Indications for Use: The Advantage-C 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 discogenic 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 Cervical Interbody Fusion Device is intended for use with supplemental fixation systems and with autogenous bone graft. The Advantage-C Cervical Interbody Fusion Device is implanted via an anterior approach.

I. Comparison to Predicate Device:

The Intelivation *Advantage-C* PEEK Cervical Interbody Fusion Device is substantially equivalent with respect to intended use and technological characteristics to the Zimmer Vista-S, cleared under K111983 & 133784 and the Zavation Interbody Fusion (IBF) System cleared under K162206. These devices all operate under the same principle of operation and with a similar form factor (PEEK cage with graft window and superior and inferior features to resist expulsion). The devices differ in geometry only, and that the proposed *Advantage-C* device is provided packaged and pre-sterilized via gamma irradiation. Intelivation asserts that any differences between the *Advantage-C* and the predicate devices do not affect safety or efficacy.

Table 1. Table of Substantial Equivalence

Parameter	Advantage-C *(Intelivation Proposed)*	Zimmer Vista-S (Predicate; K111983 & K133784)	Zavation IBF System (Reference Predicate, K162206)
Manufacturer	*Intelivation LLC*	*Zimmer*	*Zavation*
510(k) Number	*Unassigned*	*K111983 & K133784*	*K162206*
Product Code	*ODP*	*ODP*	*ODP*
Material	*Magnolia® PEEK* *Tantalum Markers*	*Optima® PEEK* *Tantalum Markers*	*Magnolia® PEEK* *Tantalum Markers*
Sizes	Heights: 6mm – 12mm Widths: 11mm – 20mm Lengths: 11mm – 15mm Parallel (0°) and Lordotic (7°)	Heights: 4mm – 12mm Widths: 11mm – 20mm Lengths: 11mm – 15mm Parallel (0°) and Lordotic (7°)	Heights: 5mm – 12mm Widths: 14mm – 16mm Lengths: 12mm – 14mm Parallel (0°) and Lordotic (6° & 10°)
Supplied Sterile?	*Yes*	*No*	*Yes*
Sterilization method	*Gamma radiation*	*N/A*	*Gamma radiation*
Intended for single use?	*Yes*	*Yes*	*Yes*
Packaging Configuration	*Tyvek-poly pouch with an outer shelf carton*	*Poly bag*	*Tyvek-poly pouch with an outer shelf carton*
Shelf Life	*12 months*	*>12 months*	*>12 months*

In addition, the proposed device was subjected to the following performance tests to support the assertion of substantial equivalence:

J. Summary of Non-Clinical Tests:

Product characterization using known standards and/or clinically relevant acceptance criteria was performed on the proposed device. A summary of this testing is provided in **Table 2** below.

70 Gruber Lane
Saint Simons Island, GA 31522
912-434-2780

Table 2. Non-Clinical Testing Information

Requirement
Subsidence Testing: ○ Subsidence characterization as defined in ASTM F2267-04 Monotonic Compressive and Torsional Strength: ○ Yield and/or ultimate force and moment characterization as defined in ASTM F2077-11 - **PASS** Dynamic Compressive and Torsional Strength: ○ Maximum runout (5×10^6 cycles) force or overall fatigue resistance as defined in ASTM F2077-11 - **PASS** Compressive and Torsional Wear Particle Analysis: ○ Wear particle size, shape, and distribution within the reported range of PEEK wear particles as defined in ASTM F1877-16 - **PASS**

K. Biocompatibility Testing:
Biocompatibility of the predicate device has been established in accordance with ISO 10993-1:2018 – *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* to demonstrate that the device is safe for permanent contact (>30 days) implantation. Refer to MAF #2735.

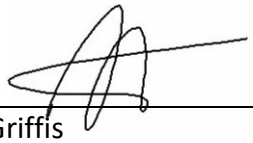
L. Sterilization:
The method employed to ensure a sterility assurance level of 10^{-6} of the proposed device is provided in **Table 3**. The sterilization process is identical to the reference predicate device.

Table 3. Sterilization Information

Test	*Test Method Summary*	*Results*
Sterilization validation	ISO/AAMI/ANSI 11137-1:2006 Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices	***Pass***
LAL	ANSI/AAMI ST72:2019, USP<161>, USP<85>, EP 2.6.14 and JP 4.01	***Pass***

M. Clinical Studies:
No human studies were necessary to prove the safety and efficacy of the device.

N. Conclusion:
The subject device demonstrated equivalent mechanical performance to the cited predicate under the same test conditions.



Jack Griffis
Regulatory Affairs
(404) 583-6889 (direct)
jackgriffisiii@gmail.com