October 29, 2021

Intelivation LLC
% Barry E. Sands
President
RQMIS, Inc.
110 Haverhill Road, Suite 524
Amesbury, Massachusetts 01913

Re: K212389
Trade/Device Name: Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 29, 2021
Received: August 2, 2021

Dear Barry Sands:

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 L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Produce 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)*
K212389

Device Name
Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF

Indications for Use *(Describe)*
The Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of nonoperative 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.

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.

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510(k) SUMMARY

Intelivation LLC's Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF

I. Submitter

Amit Sinha
Intelivation LLC
70 Gruber Lane
Saint Simons Island, GA. 31522
Phone: (484) 343-3075
Email: asinha@intelivationtech.com

CONTACT PERSON NAME AND ADDRESS

Barry E. Sands
RQMIS, Inc.
110 Haverhill Road, Suite 524
Amesbury, MA. 01913
Phone: (978) 358-7307
Email: barrysands@rqmis.com
Date Prepared: 10/22/2021

II. Subject Device

Trade name:	Advantage Lumbar System- ALIF, PLIF, DLIF, TLIF
Common name:	Intervertebral body fusion device
Classification name:	Intervertebral Body Fusion Device, Lumbar
Regulation number:	21 C.F.R. §888.3080
Classification:	Class II
Product code:	MAX

III. Predicate Devices

Cezanne Lumbar Interbody Fusion Cage System (primary predicate) (K121567)
Cezanne II Interbody Fusion System (additional predicate) (K131981)

IV. Device Description

The Advantage Lumbar – ALIF, PLIF, DLIF, TLIF's implants are interbody fusion devices intended for use as an aid in spinal fixation. These hollow, rectangular implants are offered in a variety of widths, lengths, heights, and lordotic angles designed to adapt to a variety of patient anatomies. They have serrations on the superior and inferior surfaces designed for fixation, ergonomically shaped anterior edges, and flat posterior edges. Radiopaque markers have been embedded within the implants, which are designed to allow for visualization in radiographic images.

Surgical approach

- PLIF (Posterior Lumbar Interbody Fusion) PEEK Cage System is to be implanted via posterior approach.

- TLIF (Transforaminal Lumbar Interbody Fusion) PEEK Cage System is to be implanted via transforaminal approach.
- ALIF (Anterior Lumbar Interbody Fusion) PEEK Cage System is to be implanted via anterior approach.
- DLIF (Direct Lateral Interbody Fusion) PEEK Cage System is to be implanted via direct lateral approach. It can be used in an open approach and a percutaneous approach with MIS instrumentation.

Intended Use / Indications for Use:

The Advantage Lumbar - ALIF, PLIF, DLIF, TLIF 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.

Technological Characteristics:

The Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF consists of PEEK+Tantalum which is identical to its predicate devices. The design, material composition and manufacturing are same as the predicate devices.

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

The Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF and the Cezanne Lumbar Interbody Fusion Cage System (primary predicate) and Cezanne II Interbody Fusion System (additional predicate) have identical intended use/indications for use, technological characteristics, and principles of operation. There are no technological differences between the Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF and its predicate devices resulting in no new issues of safety or effectiveness. Thus, the subject device is identical to predicate devices.

VI. Performance Data

The subject and predicate devices are identical and therefore, no performance testing is required. Submission is only transferring names of systems that have already been cleared under K121567 and K131981. No testing is required.

VII. Conclusion

The Advantage Lumbar System - ALIF, PLIF, DLIF, TLIF and its predicate devices have identical intended use/indications for use, technological characteristics, and principles of operation. Thus, the subject device is substantially equivalent to its primary predicate, the Cezanne Lumbar Interbody Fusion Cage System (K121567).