August 27, 2021

K&J Consulting Corporation
℅ Barry Sands
President
RQMIS Inc.
110 Haverhill Road, Suite 524
Amesbury, Massachusetts 01913

Re: K212038
Trade/Device Name: K&J IVA (ACIF, DLIF, PLIF, TLIF, ALIF) PEEK Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: June 29, 2021
Received: June 30, 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 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)*

K212038

Device Name

K&J IVA (ACIF, PLIF, TLIF, DLIF and ALIF) PEEK Cage

Indications for Use *(Describe)*

The K&J IVA (ACIF) PEEK Cage 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-TI 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.

The K&J IVA (PLIF, TLIF, DLIF and ALIF) PEEK Cage 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 one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. 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

DIO Medical Co., Ltd's IVA PEEK Cage

I. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

K&J Consulting Corporation
2260 Glenview Dr,
Lansdale
PA 19446
US
Phone: (267)-438-9293
Email: kj.pd2021@gmail.com

II. Contact Person Name and Address:

Barry Sands
RQMIS, Inc.
110 Haverhill Road, Suite 524
Amesbury, MA. 01913
Phone: (978) 358-7307
Facsimile: (978) 477-0206
Email: barrysands@rqmis.com

III. Subject Device:

Trade Name:	K&J IVA (ACIF, DLIF, PLIF, TLIF, ALIF) PEEK Cage
Common Names:	Intervertebral body fusion device
Classification:	Class II
Classification Name:	Intervertebral Body Fusion Device, Cervical (Product Code ODP) Intervertebral Body Fusion Device, Lumbar (Product Code MAX)
Regulation Number:	21 C.F.R. §888.3080

IV. Predicate Devices:

DIO Medical IVA (ACIF, DLIF, PLIF, TLIF, ALIF) PEEK Cage (K162220)

V. Device Description:

Intended Use / Indications for Use

Indications for Use:

The **K&J IVA (ACIF) PEEK Cage** is intended to be used 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-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device 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

The **K&J IVA (PLIF, TLIF, DLIF and ALIF) PEEK Cage** is indicated for intervertebral body fusion of the lumbar spine, L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. 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 **K&J IVA (ACIF, PLIF, TLIF, DLIF and ALIF) PEEK Cage** consists of PEEK+Tantalum which is identical to its predicate devices. The design, material composition and manufacturing are same as the predicate.

VI. Comparison of Technological Characteristics with the Predicate Device: (Substantial Equivalence)

The K&J IVA (ACIF, PLIF, TLIF, DLIF and ALIF) PEEK Cage is identical to the predicate device and is as safe and effective as the DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) PEEK Cage. The Subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. There are no technological differences between the Subject device and its predicate devices resulting in no new issues of safety or effectiveness. Thus, the K&J IVA (ACIF, PLIF, TLIF, DLIF and ALIF) PEEK Cage is identical/substantially equivalent.

VII. Performance Data

The subject and predicate devices are identical and therefore, no performance testing is required. Submission is only transferring name of a system that has already been cleared under K162220. No testing is required.

VIII. Conclusion:

The K&J IVA (ACIF, PLIF, TLIF, DLIF and ALIF) PEEK Cage has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Thus, the subject device is identical/substantially equivalent to the predicate device.