DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 21, 2016

DIO Medical Co., Ltd
% Mr. Paul Speidel
Senior Regulatory and Quality Consultant
RQMIS Inc.
110 Haverhill Road, Suite 526
Amesbury, MA 01913

Re: K162220
Trade/Device Name: DIO Medical IVA (ACIF, DLIF, PLIF, TLIF, ALIF) Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: September 9, 2016
Received: September 12, 2016

Dear Mr. Speidel:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162220

Device Name
DIO Medical IVA (ACIF, DLIF, PLIF, TLIF, ALIF) Cage

Indications for Use *(Describe)*
The DIO Medical IVA (ACIF) 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 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 DIO Medical IVA (PLIF, TLIF, DLIF and ALIF) 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 or two contiguous 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.

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 Cage

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

DIO Medical Co., Ltd
Sung Hee-Lee
101-105 Megacenter, SK Technopark
124 Sagimakgol-ro, Jungwon-gu Seongnam-si
Gyeonggi-do, South Korea

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Contact Person: Sung Hee-Lee

Date Prepared: November 10, 2016

Name of Device and Name/Address of Sponsor

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

DIO Medical Co., Ltd
Sung Hee-Lee
101-105 Megacenter, SK Technopark
124 Sagimakgol-ro, Jungwon-gu Seongnam-si
Gyeonggi-do, South Korea

Common or Usual Name

Intervertebral Body Fusion Device

Classification Name, Product Code, Regulation Number and Class

Intervertebral Body Fusion Device, Cervical (Product Code ODP) 21 CFR 888.3080 Class II
Intervertebral Body Fusion Device, Lumbar (Product Code MAX) 21 CFR 888.3080 Class II

Predicate Devices

- Primary
  - K122872 Galaxy PEEK Cage (Dio Medical Co., Ltd)
- Additional
  - K111820 Synster Cage (BM Korea Co., Ltd)
  - K110783, K120063, K121096 VENUS Lumbar Intervertebral Body Fusion Cage System (L&K Biomed Co.)
  - K120464 Innesis PEEK Cage (BK Meditech Co.)
  - K131612, K131612, K153517 AnyPlus PEEK Cage (GS Medical Co., Ltd.)

Intended Use / Indications for Use

Indications for Use:

The DIO Medical IVA (ACIF) 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 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 DIO Medical IVA (PLIF, TLIF, DLIF and ALIF) 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 or two contiguous 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.

Intended Use:

The DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage are intended for intervertebral body fusion in skeletally mature patients. The intended operation of this device is concentrated around the C2-C3, C7-TI, and L2-S1 region of the spine. The device is designed for use with supplemental fixation and with autograft to facilitate fusion in the vertebrae.

Technological Characteristics

The **DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage** consists of PEEK+Tantalum which is identical to its predicate devices. All of the heights, lengths, and widths are within range covered by its predicate devices.

Performance Data

The **DIO Medical IVA (ACIF) Cage** device underwent testing according to ASTM F2077, specifically static and dynamic axial compression testing, static and dynamic torsion testing, static compression shear testing; and subsidence testing according to ASTM F2267.

The **DIO Medical IVA (PLIF, TLIF, DLIF and ALIF) Cage** device underwent testing according to ASTM F2077, specifically static and dynamic axial compression testing, static torsion testing, static compression shear testing; and subsidence testing according to ASTM F2267.

Substantial Equivalence

The **DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage** is as safe and effective as the Galaxy PEEK Cage (DIO Medical Co., Ltd), SYNSTER Cage (BM Korea Co., Ltd), VENUS Lumbar Intervertebral Body Fusion Cage System (L&K Biomed Co.), the Innesis PEEK Cage (BK Meditech Co.) and the AnyPlus PEEK Cage (GS Medical Co., Ltd.). The **DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage** has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the **DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage** and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the **DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage** is as safe and effective as the Galaxy PEEK Cage (DIO Medical Co., Ltd), SYNSTER Cage (BM Korea Co., Ltd), VENUS Lumbar Intervertebral Body Fusion Cage System (L&K Biomed Co.), the Innesis PEEK Cage (BK Meditech Co.) and the AnyPlus PEEK Cage (GS Medical Co., Ltd.). Thus, the **DIO Medical IVA (ACIF, PLIF, TLIF, DLIF and ALIF) Cage** is substantially equivalent.