DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 16, 2017

DIO Medical Co., Ltd.
Mr. Jaewon Jang
Manager
8770 West Bryn Mawr Avenue, Suite 1250
Chicago, Illinois 60631

Re: K162849
Trade/Device Name: Huvex Interspinous Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: January 27, 2017
Received: January 30, 2017

Dear Mr. Jang:

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)*
K162849

Device Name
Huvex Interspinous Fixation System

Indications for Use *(Describe)*
The Huvex Interspinous Fixation System is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Huvex Interspinous Fixation System is intended for use at one level, in conjunction with autogenous bone graft, and not intended for stand-alone 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.

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510(k) SUMMARY

DIO Medical Co., Ltd.

Huvex Interspinous Fixation System

Sponsor:		DIO Medical Co., Ltd. 8770 West Bryn Mawr Avenue, Suite 1250 Chicago, Illinois 60631
	Official Contact: Phone:	Jaewon Jang 847-795-1078 ext. 103
	Date Prepared:	February 15, 2017

Device Name:	Huvex Interspinous Fixation System
Common Name:	Spinous Process Plate
Classification Name:	Spinal interlaminal fixation orthosis
Classification Number:	21 CFR 888.3050
Product Code/Classification:	PEK, class II

Description:

The Huvex Interspinous Fixation System consists of a left plate, a right plate, pin, bolt, inner cap, center bar, and set screw. Each of these components is provided in several sizes to allow for the construction of five different Huvex Interspinous Fixation implant sizes. The left plate is provided assembled with the poly axial bar. The bar has a bone graft window to allow fusion between spinous process. Poly axial bar is also designed to fit the anatomical characteristics of the spinous process. The right plate is designed to be combined with left plate fixed to spinous process. Right plate contains a set screw to lock the right plate to the poly axial bar. The Huvex Interspinous Fixation System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136.

In addition to the implants a set of reusable surgical instruments are provided. Both implant and instruments have trays that are used for handling and storage.

Intended Use:	The Huvex **Interspinous Fixation System** is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The **Huvex Interspinous Fixation System** is intended for use at one level, in conjunction with autogenous bone graft, and not intended for stand-alone use.
Performance Data:	Static & Dynamic compression, Static torsion, and Static tension testing in accordance with a modified ASTM F1717 setup, in addition Static grip testing with a modified ASTM F1798 setup were conducted to demonstrate substantial equivalence to the predicate system(s).
Predicate Device:	Primary predicate: Globus Medical- Sp-Fix Spinous Process Fixation Plate (K102195) Additional predicates: Medtronic - CD Horizon SPIRE™ Spinous Process Plate (K032037), NuVasive - Affix I & II Spinous Process Plate system (K131238 & K143388), Alphatec Spine - Bridgepoint Spinous Process System (K103205) and Life Spine - Aileron posterior fusion system (K140236)
Performance and SE Determination:	The Huvex Interspinous Fixation System has been demonstrated to be substantially equivalent to the predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s).