April 26, 2018

Huvexel Co., Ltd.
% Michael A. Patz, MBA, RAC
Senior Regulatory/Quality Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K173201
Trade/Device Name: UNITY Sacroiliac Joint Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: March 28, 2018
Received: April 2, 2018

Dear Mr. Patz:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173201

Device Name
UNITY Sacroiliac Joint Fixation System

Indications for Use *(Describe)*
The UNITY Sacroiliac Joint Fixation System is indicated for use in skeletally mature patients for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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Huvexel's UNITY Sacroiliac Joint Fixation System

I. SUBMITTER

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Contact Person: Sung Hee-Lee, Quality Management Representative and Deputy Manager of Huvexel Co., Ltd.

Date Prepared: September 28, 2017

II DEVICE

Name of Device: UNITY Sacroiliac Joint Fixation System

Common or Usual Name: Sacroiliac Joint Fixation Screw

Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

Regulatory Class: II

Product Code: OUR

III PREDICATE DEVICE

Primary Predicate: Globus Medical – SI-LOK Sacroiliac Joint Fixation System (K112028)

Additional Predicates: Depuy-Synthes – Synthes Cannulated Screw System (K021932 & K962011)

IV DEVICE DESCRIPTION

The UNITY Sacroiliac Joint Fixation System consists of screws designed to enhance sacroiliac joint fusion. The UNITY Sacroiliac Joint Fixation System is offered in various diameters, lengths, and three screw types in cannualated form to accommodate patient anatomy. The three design types of the subject device are:

1. Standard Thread Screw (with and without slots)
2. Lag Screw (with and without slots) and

3. Washer Screw (with slots)

V INDICATIONS FOR USE

The UNITY Sacroiliac Joint Fixation System is indicated for use in skeletally mature patients for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

VI COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements:

- Consist of a screw and a washer
- Minimally invasive placement procedure
- Device inserted percutaneously
- Use of a permanent implant for bone fixation
- Mechanically securing the fixation by a permanent implant screw

There are no know technological differences between the subject and predicate devices other than the range of screw sizes offered.

VII PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

UNITY Sacroiliac Joint Fixation System contains the following contact metallic fastener screw and washer components: titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and Cobalt-Chromium-Molybdenum (CoCr) per ASTM F1537. The biocompatibility of the UNITY Sacroiliac Joint Fixation System is based on FDA's clearance of the Rexious Spinal Fixation System (K111362) that contains tissue contact materials for similar uses. The Biocompatibility Assessment for the Unity Sacroiliac Joint Fixation System demonstrates that the the Unity Sacroiliac Joint Fixation System utilizes the same manufacturing processes, materials, sterilization and similar geometry for Huvexel's

(formerly Dio Medical, Inc.) Rexious spinal fixation system (K111362), which provides the rationale for the UNITY Sacroiliac Joint Fixation System's sterilization and biocompatibility.

Mechanical Testing

Three motion and stress tests were performed:

1. Dynamic Cantilever Test,
2. Static Cantilever Test,
3. Static Axial Pullout Test, and
4. Static Torsion Test.

Standards Applied

Performance Standard

ASTM F2193-14, Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System (Static and Dynamic Cantilever)

ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws (Static Axial Pullout and Static Torsion)

In all instances, the UNITY Sacroiliac Joint Fixation System functioned as intended and stability observed was as expected.

VIII CONCLUSIONS

The UNITY Sacroiliac Joint Fixation System is substantially equivalent to the Globus Medical– SI-LOK Sacroiliac Joint Fixation System (K112028), and the Depuy-Synthes – Synthes Cannulated Screw System (K021932 & K962011). The UNITY Sacroiliac Joint Fixation System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the UNITY Sacroiliac Joint Fixation System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the UNITY Sacroiliac Joint Fixation System is as substantially equivalent to the predicate devices.