U&I Corporation
Jee-Ae Bang
RA Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
Korea

February 4, 2019

Re: K190067
Trade/Device Name: Velofix™ Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: January 14, 2019
Received: January 15, 2019

Dear Jee-Ae Bang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Katherine D. Kavlock -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)*
K190067

Device Name
Velofix™ Interbody Fusion System

Indications for Use *(Describe)*

The Velofix PEEK Cervical 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-T1 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 weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Velofix PEEK Lumbar Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease(DDD) at one or two levels for L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation.

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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## 6. 510(k) Summary

**Manufacturer:** U & I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 11781

**Sponsor:** U & I Corporation
20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 11781

**Sponsor Contact:** Jee-Ae Bang, RA Specialist
+82-31-860-6846
bbangzhi@youic.com

**Date Prepared:** February 01, 2019

**Device Name:** Trade Name: Velofix™ Interbody Fusion System

**Classification Name:** Spinal Intervertebral Body Fusion Device, Cervical , per 21 CFR 888.3080

**Common Name:** Intervertebral Body Fusion Device, IBF Device

**Product Code:** ODP, MAX

**Predicate Device:** Velofix™ Interbody Fusion System (K171749)

**Purpose of submission:**

This submission is to introduce sterilized implants of the Velofix™ Interbody Fusion System (established category A).

**Description of Device:**

The Velofix™ Interbody Fusion System consists of implants available in various heights, width and angle with an open architecture to accept packing of autogenous bone graft and consist of:

1) Cervical Interbody Fusion Device (Velofix™ PEEK Cervical Cage), which may be implanted as a single device via an anterior approach.
2) Lumbar Interbody Fusion Device (Velofix™ PEEK Lumbar Cage), which may be implanted.

The implants are made of radiolucent polymer polyether-ether-ketone(ASTM F2026) body with the x-ray markers made of tantalum markers (ASTM F560), and they can be supplied either sterile or non-sterile.

**Indications for Use:**
The Velofix™ PEEK Cervical 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-T1 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 weeks of non-operative treatment prior to treatment with an intervertebral cage.

The Velofix™ PEEK Lumbar Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease(DDD) at one or two levels for L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation.

**Substantial Equivalence:**

The subject device is substantially equivalent to Velofix™ Interbody Fusion System (Cleared: K171749) in design, material, mechanical performance, function and intended use.

1. Comparison Technological Characteristics

The predicate and subject device have the same intended use and basic fundamental scientific technology and share the following similarities;

- The same indications for use
- The same design features
- The same materials
- The equivalent mechanical performance

2. Sterilization

The only difference of the subject device from the predicate device is the sterilization. The following properties were evaluated to assess that no new safety and efficiency issues were raised with this new type of device.

(1) Sterility according to ISO11137-2
(2) Packaging integrity according to ASTM F1929, ASTM F2096 and etc.
(3) Pyrogenicity according to ISO 10993-11
(4) Biocompatibility according to ISO 10993-1
(5) Shelf-life according to ASTM F1980

3. Conclusion

The data and information provided in this submission support the conclusion that the sterilized Velofix$^{TM}$ Interbody Fusion System is substantially equivalent to predicate device with respect to indications for use and technological characteristics and no new safety and efficiency was found due to the sterilization.