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

July 10, 2019

Re: K183243
Trade/Device Name: Velofix™ TLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 7, 2019
Received: June 10, 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/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,

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

510(k) Number *(if known)*
K183243

Device Name
Velofix™ TLIF Cage

Indications for Use *(Describe)*
The Velofix™ TLIF Cage is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The Velofix™ TLIF Cage is to be used with supplemental internal spinal fixation. Additionally, the Velofix™ TLIF Cage is to be used with autogenous bone graft material.

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

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

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

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

Date Prepared: November 20, 2018

Device Name: Trade Name: Velofix™ TLIF Cage

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

Common Name: Intervertebral Body Fusion Device, IBF Device

Product Code: MAX

Predicate Device:
Primary - Velofix™ TLIF Cage (K172419)
Additional - Velofix™ TLIF Cage (K181829)
Additional - Velofix™ Interbody Fusion System (K140864)

Purpose of submission:
This submission is to introduce a titanium alloy (per ASTM F136) with expanded graft window of the Velofix™ TLIF Cage.

Description of Device:

The Velofix™ TLIF Cage consists of implants available in various heights, width, length and angle with an open architecture to accept packing of auto bone graft material. The Velofix™ TLIF Cage may be implanted a single device via a transforaminal approach and adopted to the anterior anatomy of the vertebral endplates.
The Velofix™ TLIF Cage device has two types: the one is consisted of cage body

(PEEK), articulating component (Ti Alloy) and radiographic markers (Tantalum); the other is consisted of cage body and articulating component made of Ti Alloy. The articulating component is for attachment to the inserter instrument to allow the cage to pivot to the final positioning.

The Velofix™ TLIF Cage has 3 types as follows:

1) TLIF Cage, which is made of Polyether-ether-ketone (PEEK);
2) TLIF Ti Cage, which is made of Titanium alloy (Ti6Al4V ELI);
3) TLIF Ti LW Cage, which is made of Titanium alloy (Ti6Al4V ELI) with the expanded graft window of the side part.

The Velofix™ TLIF Cage is implanted by using the instruments manufactured from stainless steel materials that conform to ASTM F899.

Indications for Use:

The Velofix™ TLIF Cage is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Velofix™ TLIF Cage is to be used with supplemental internal spinal fixation. Additionally, the Velofix™ TLIF Cage is to be used with autogenous bone graft material.

Substantial Equivalence:

Velofix™ TLIF Cage is substantially equivalent to Velofix™ TLIF Cage (K172419), Ti alloy version of Velofix™ TLIF Cage (K181829), and Velofix™ Interbody Fusion System (K140864) in design, material, mechanical performance, function and intended use.

1. Comparison Technological Characteristics

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

- The same indications for use
- Similar design features
  - Pyramidal teeth on superior and inferior surfaces.
  - Self-distracting nose which allows for insertion.
  - Articulation mechanism which allows the cage to pivot to final positioning.
  - Large graft cavity for bone graft packing to help aid in the fusion process.
  - Anterior and posterior side holes.
  - Various lordosis angles

- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

The axial compression and compression shear testing per ASTM F2077 was conducted to compare data of proposed device of the Velofix™ Interbody Fuson System (K140864) and to verify there are no new safety and effectiveness issues were not raised by the proposed device.

3. Conclusion

The data and information provided in this submission support the conclusion that the Velofix™ TLIF Cage is substantially equivalent to predicate devices with respect to indications for use and technological characteristics.