November 19, 2021

U&I Corporation
Young-eun Lee
RA Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
South Korea

Re: K210573
Trade/Device Name: Velofix™ SA Cervical Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: October 13, 2021
Received: October 18, 2021

Dear Young-eun Lee:

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,

Brent Showalter, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210573

Device Name
Velofix™ SA Cervical Cage

Indications for Use *(Describe)*
The Velofix™ SA Cervical Cage is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-Tl disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Velofix™ SA Cervical Cage implants are to be used with either autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and implanted via an open, anterior approach. The Velofix™ SA Cervical Cage must be used with the internal screw fixation provided by screws of the Velofix™ SA Cervical Cage. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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
K210573

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: Young-eun Lee, RA Specialist
+82 31 860 6927
youngeun@youic.com

Date Prepared: October 13, 2021

Device Name: Trade Name: Velofix™ SA Cervical Cage

Classification Name: Intervertebral Fusion Device With Integrated Fixation, Cervical , per 21 CFR 888.3080

Common Name: Intervertebral Body Fusion Device, IBF Device

Product Code: OVE

Predicate Devices:
Primary - Velofix™ SA Cervical Cage (K172424)
Additional - Galaxy (ACIF, PLIF, TLIF and ALIF) Peek cage (K122872)

Purpose of submission:
This submission is to add new device to the original device, which the assembly method of spacers and plates with the increased length is different from the original device.

Description of Device:
The Velofix™ SA Cervical Cage consists of spacers, screws, locking plate and set screw.

The spacers are available in various heights, width and have only 7˚ lordotic angle with an open architecture to accept packing of autograft or autogenous bone graft, while the medical grade titanium alloy screws have various diameters and length for fixing the spacers. The locking plate, made of radiolucent PEEK and titanium alloy, is to prevent screw loosening. The medical grade titanium alloy set screw is intended

for fixation of the locking plate.

The Velofix™ SA Cervical Cage has three types:

1) All PEEK Type
   The spacer which is made of radiolucent PEEK spacer (polymer polyether-ether-ketone, ASTM F2026) with the tantalum markers (ASTM F560).
2) Ti plate Type
   The spacer which is a combination of radiolucent PEEK spacer with the x-ray markers and medical grade titanium alloy plate (Ti6Al4V ELI, ASTM F136).
3) Ti plate-N type

   The spacer which is a combination of radiolucent PEEK spacer with the x-ray markers and medical grade titanium alloy plate (Ti6Al4V ELI, ASTM F136). Before surgery, the user can choice and assemble PEEK spacers and titanium alloy plates in order to size through patient's bone condition.

The Velofix™ SA Cervical Cage is implanted as a single device via an anterior approach.

Indications For Use:

The Velofix™ SA Cervical Cage is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Velofix™ SA Cervical Cage implants are to be used with either autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and implanted via an open, anterior approach. The Velofix™ SA Cervical Cage must be used with the internal screw fixation provided by screws of the Velofix™ SA Cervical Cage. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Substantial Equivalence:

The Velofix™ SA Cervical Cage is substantially equivalent to Velofix™ SA Cervical Cage (K172424) and Galaxy ACIF Cage (K122872) in design, material, mechanical performance, function and intended use.

The mechanical performance of Velofix™ SA Cervical Cage met the acceptance criteria which have been established from the predicate devices.

1. Comparison Technological Characteristics

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

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

The mechanical strength evaluation was conducted to compare data of proposed device of the Velofix^{TM} SA Cervical Cage (K172424) and Galaxy ACIF Cage (K122872) 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^{TM} SA Cervical Cage is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.