## 5. 510(k) Summary

JUL 2 2 2014

| | |
|---|---|
| **Manufacturer:** | U & I Corporation<br>20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859 |
| **Sponsor:** | U & I Corporation<br>20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859 |
| **Sponsor Contact:** | Ji Yea Lee, Regulatory Affairs Assistant<br>+82 31 852 0102 (ext.632)<br>jylee@youic.com |
| **Date Prepared:** | April 01, 2014 |
| **Device Name:** | Trade Name: Velofix™ Interbody Fusion System |
| **Classification Name:** | Spinal Intervertebral Body Fusion Device, Cervical<br>Spinal Intervertebral Body Fusion Device, Lumbar<br>, per 21 CFR 888.3080 |
| **Common Name:** | Intervertebral Body Fusion Device, IBF Device |
| **Product Code:** | ODP, MAX |
| **Predicate Devices:** | Velofix™ Interbody Fusion System(K132926)<br>Galaxy PLIF PEEK Cage (K122872)<br>Capstone Spinal System (K082342) |

**Description of Device:**

The Velofix™ Interbody Fusion System(K132926) 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.
   - o Bilaterally via a posterior(PLIF) approach;
   - o As a single device via a transforaminal(TLIF) approach;

The Velofix™ Interbody Fusion System(Pending:K140864) contains additional sizes in PEEK Lumbar cages of The Velofix™ Interbody Fusion System(Cleared:

K132926).
The implants are made of radiolucent polymer polyether-ether-ketone(PEEK-OPTIMA LT 1, ASTM F2026) body with the x-ray markers made of tantalum markers (ASTM F560). The Velofix™ PEEK Lumbar Cage is implanted by using the instruments manufactured from stainless steel materials that conform to ASTM F899.

**Intended 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 discongenic 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 additional size of Velofix™ Interbody Fusion System is substantially equivalent to Velofix™ Interbody Fusion System(Cleared:K132926), Galaxy PLIF PEEK Cage (K122872), and Capstone Spinal System (K082342) in design, material, mechanical performance, function and intended use.

The mechanical performance of The additional size of Velofix™ Interbody Fusion System 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 additional size of Velofix™ Interbody Fusion System was tested in a non clinical setting (bench testing) to assess that to no new safety and efficiency issues were raised with this device. The testing met all acceptance criteria and verifies that performance of the The additional size of Velofix™ Interbody Fusion System is substantially equivalent to predicate devices.

The following tests were performed:

(1) Static compression test according to ASTM F2077
(2) Dynamic compression test according to ASTM F2077

3. Conclusion

The data and information provided in this submission support the conclusion that the Velofix™ Interbody Fusion System(K140864) is substantially equivalent to predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 22, 2014

U & I Corporation
Ms. Ji Yea Lee
Regulatory Affairs Assistant
20, Sandan-ro, 76beon-gil (Rd)
Uijeongbu-si, Gyeonggi-do
Republic of Korea 480-859

Re: K140864
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: ODP, MAX
Dated: April 22, 2014
Received: April 28, 2014

Dear Ms. 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. 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 yours,

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140864

Device Name
VelofixTM Interbody Fusion System

Indications for Use *(Describe)*
The VelofixTM 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 to facilitate fusion. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral cage.

The VelofixTM 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 discongenic 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

**Katherine D. Kavlock, PhD**
**Division of Orthopedic Devices**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*