U&i Corporation
Yeon-Jung Choi
Regulatory Affairs Specialist
20, Sandan-ro 76 eon-gil(Rd)
Uijeongbu-si, 11781 Kr

Re: K173198
Trade/Device Name: Facet Screw Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: December 20, 2017
Received: December 22, 2017

Dear Yeon-Jung Choi:

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,

Colin O'neill -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)*
K173198

Device Name
Facet Screw Fixation System

Indications for Use *(Describe)*
The Facet Screw Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of facet joints. The Facet Screw Fixation System is indicated for posterior surgical treatment with or without bone graft at single or multiple levels from C2 to S1 (inclusive). For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The Facet Screw Fixation System is indicated for treatment for any or all of the following:

Spondylolisthesis
Spondylolysis
Pseudoarthrosis or failed previous fusions which are symptomatic
Degenerative Disc Disease (DDD) as defined by back pain of discogenic origin with degeneration of the disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability
Trauma including spinal fractures and/or dislocations

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:	Yeon-Jung Choi, Regulatory Affairs Specialist +82 31 860 6838 yjchoi@youic.com
Date Prepared:	December 26, 2017
Device Name:	Trade Name: Facet Screw Fixation System
Classification Name:	Unclassified
Common Name:	System, Facet Screw Spinal Device
Product Code:	MRW
Predicate Devices:	NuVasive™ Triad™ Facet Screw System (K020411) [Primary] Resolute Facet Screw System (K121551) DISCOVERY Facet Screw Fixation System(K012773)

Description of Device:

The Facet Screw Fixation System is manufactured by U&I Corporation. The Facet Screw Fixation System is a set of screws used for translaminar or transfacet fixation in the spine as an adjunct for fusion. The Facet Screw Fixation System consists of screws and washer. The screws are provided in two diameters and each diameter screw is provided in multiple lengths to accommodate the various anatomy of the spine. The washer is provided to help compression for bone fusion. The screw is cannulated to aid in placement via K-WIRE. All implant components are made of titanium alloy in accordance with ASTM F 136. The Facet Screw Fixation System is intended to provide immobilization and stabilization of the facet articular process to support fusion with minimal invasion.

Indications For Use:
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- Spondylolysis
- Pseudoarthrosis or failed previous fusions which are symptomatic
- Degenerative Disk Disease (DDD) as defined by back pain of discogenic origin with degeneration of disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability
- Trauma including spinal fractures and/or dislocations.

Substantial Equivalence:
Facet Screw Fixation System is substantially equivalent to Resolute Facet Screw System (K121551), NuVasive™ Triad™ Facet Screw System (K020411) and DISCOVERY Facet Screw Fixation System (K012773) in design, material, mechanical performance, function and intended use. The primary predicate device is the NuVasive™ Triad™ Facet Screw System, and the others are additional predicate devices.

The mechanical performance of the Facet Screw Fixation System demonstrated substantial equivalence to 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 materials
- The equivalent mechanical performance

2. Performance Testing

The Facet Screw Fixation 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. Performance testing verifies performance of the Facet Screw Fixation System is substantially equivalent to predicate devices.

The following tests were performed:

(1) Static torsion test according to ASTM F543-13
(2) Driving torque test according to ASTM F543-13
(3) Static pullout test according to ASTM F543-13
(4) Static bending test according to ASTM F2193-14
(5) Dynamic bending test according to ASTM F2193-14

3. Conclusion

The data and information provided in this submission support the conclusion that the Facet Screw Fixation System is substantially equivalent to predicate devices with respect to indications for use and technological characteristics.