DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 30, 2016

U&I Corporation
Ms. Ji Yea Lee
Regulatory Affairs Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do
KOREA 11781

Re: K162189
Trade/Device Name: ANAX™ 5.5 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: August 2, 2016
Received: August 4, 2016

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 CFRParts 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,

Mark N. Melkerson -S

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)*
K162189

Device Name
ANAX™ 5.5 Spinal System

Indications for Use *(Describe)*
The ANAX™ 5.5 Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

Spondylolithesis (Grade 3 and 4)
Degenerative spondylolisthesis with objective evidence of neurological impairment
Trauma (i.e., fracture or dislocation)
Spinal stenosis
Defomities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
Tumor
Pseudoarthrosis
Failed previous fusion

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, Korea, 11781

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

Sponsor Contact: **J**i Yea Lee, Regulatory Affairs Specialist
+82-31-860-6837
jylee@youic.com

Date Prepared: Aug 23, 2016

Device Name: ANAX™ 5.5 Spinal System

Classification Name: Pedicle screw spinal system, per 21 CFR 888.3070

Common Name: Pedicle screw spinal fixation system

Product Code: MNH, MNI (Class II)

Primary Predicate: ANAX™ 5.5 Spinal System (K132101)
Additional Predicate: ANAX™ 5.5 Spinal System (K143417)

Description of Device:

The ANAX™ 5.5 Spinal System is manufactured by U&I corporation. The ANAX™ 5.5 Spinal System is a top-loading multiple component, posterior spinal fixation system and minimally invasive surgery system which consist of pedicle screws, rods, set screws, connectors and a transverse (cross) linking mechanism. The ANAX™ 5.5 Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The ANAX™ 5.5 Spinal System components are supplied non-sterile, single use and are fabricated from medical grade titanium alloy (ASTM F136) and medical grade cobalt-chromium-molybdenum alloy (ASTM F1537). All pedicle screws have self-tapping function in ANAX™ 5.5 spinal System. The double lead thread is applied to the all pedicle screws to shorten the operation time. ANAX™

5.5 Spinal System with CoCr rods may be used to provide immobilization and stabilization of spinal segment when the rigid system is need. (Recommendation: trauma or deformities) The product life time of ANAX™ 5.5 SPINAL SYSTEM is 2 years based on mechanical test result.

MIS Extended Screw, Set Screw for MIS, and Straight and Curved MIS Rod have newly added in the system and they are intended for use in minimally invasive surgery (MIS).

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of ANAX™ 5.5 Spinal System implants.

Indications for Use:

The ANAX™ 5.5 Spinal System is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Spondylolisthesis (Grade 3 and 4)
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Substantial Equivalence:

ANAX™ 5.5 Spinal System is substantially equivalent to the ANAX™ 5.5 Spinal System (K132101, K143417) in design, material, mechanical performance, function and intended use.

The mechanical performance of ANAX™ 5.5 Spinal 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 Justification

Additional mechanical testing (bench testing) was not conducted on the ANAX™ 5.5 Spinal System. However, the justification report was conducted to compare data of modified device to the ANAX™ 5.5 Spinal System (K132101, K143417) and determined no new worst case was introduced.

The data met all acceptance criteria and verifies that performance of the ANAX™ 5.5 Spinal System is substantially equivalent to the predicate devices.

3. Conclusion

The data and information provided in this submission support the conclusion that the ANAX™ 5.5 Spinal System is substantially equivalent to its predicate device with respect to indications for use and technological characteristics.