



December 12, 2018

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

Re: K183383

Trade/Device Name: ANAX™ OCT Spinal System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: December 3, 2018
Received: December 6, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K183383

Device Name

ANAX™ OCT Spinal System

Indications for Use (Describe)

ANAX™ OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. ANAX™ OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, ANAX™ OCT Spinal System may be connected to Perfix™ Spinal System and ANAX™ 5.5 Spinal System rods with the rod connectors. Transition rods with differing diameters may also be used to connect ANAX™ OCT Spinal System to Perfix™ Spinal System and ANAX™ 5.5 Spinal System.

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

Date Prepared: December 03, 2018

Trade Name: ANAX™ OCT Spinal System

Classification Name: Spinal Interlaminar Fixation Orthosis

Classification: Unclassified

Common Name: Occipito-cervico-thoracic Spinal Fixation System

Product Code: NKG, KWP

Predicate Device: ANAX™ OCT Spinal System (K150570)

Description of Device:

The ANAX™ OCT Spinal System is manufactured by U&I corporation. The ANAX™ OCT Spinal System is for fixation the cervicocranium (Occiput/C2), the true subaxial region (C3/C6), and the cervicothoracic junction (C7 to T2) by one system. The ANAX™ OCT Spinal System consists of polyaxial screws, polyaxial shank screws, hooks, rods, set screws, transverse (cross) links and occipital plate. Connectors are also provided for surgical convenience. The ANAX™ OCT Spinal System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The single-use ANAX™ OCT Spinal System components are supplied as non-sterile and are fabricated from medical grade titanium alloy (ASTM F136). All polyaxial screws have self-tapping function in the ANAX™ OCT Spinal System. Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the ANAX™ OCT Spinal System implants.

Indications for Use:

ANAX™ OCT Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine(C1 to C7) and the thoracic spine from T1-T3:

ANAX™ OCT Spinal System



traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g.pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. ANAX™OCT Spinal System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, ANAX™ OCT Spinal System may be connected to Perfix™ Spinal System and ANAX™ 5.5 Spinal System rods with the rod connectors. Transition rods with differing diameters may also be used to connect ANAX™ OCT Spinal System to Perfix™ Spinal System and ANAX™ 5.5 Spinal System.

Substantial Equivalence:

ANAX™ OCT Spinal System is substantially equivalent to ANAX™ OCT Spinal System (K150570) in design, material, mechanical performance, function and intended use.

The mechanical performance of the ANAX™ OCT Spinal System, made of Ti Alloy, met the acceptance criteria which have been established from the predicate devices.

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

2. Performance Testing

Any mechanical test in non clinical setting (bench testing) was not conducted on the ANAX™ OCT Spinal System. However, the mechanical strength evaluation was conducted to compare data of proposed device of the ANAX™ OCT Spinal System(K150570) and to verify there are no new safety and effectiveness issues were not raised by the proposed device. The data met all acceptance criteria and that verifies performance of the ANAX™ OCT Spinal System is substantially equivalent to predicate devices.

3. Conclusion

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