



December 13, 2018

U&I Corporation
Ms. Jee-Ae Bang
Regulatory Affairs Assistant Manager
20, Sandan-ro 76beon-gil (Road)
Uijeongbu-si, Gyeonggi-do 11781
KOREA

Re: K181824
Trade/Device Name: CBT Screw Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: November 23, 2018
Received: November 26, 2018

Dear Ms. Bang:

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)

K181824

Device Name

CBT Screw Fixation System

Indications for Use (Describe)

The CBT Screw Fixation 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
- 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

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.

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."

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: Jee-Ae Bang, Regulatory Affairs Assistant Manager
+82 31 860 6846
bbangzhi@youic.com

Date Prepared: July 06, 2018

Device Name: Trade Name: CBT Screw Fixation System

Classification Name: Thoracolumbosacral Pedicle Screw System,
per 21CFR 888.3070

Common Name: Thoracolumbosacral Pedicle Screw System,

Product Code: NKB

Predicate Devices: ANAX™ 5.5 Spinal System (K132101)

Description of Device:

The Cortical Bone Trajectory(CBT) Screw Fixation System(hereinafter referred to as “CBT Screw Fixation System”) is manufactured by U&I corporation. The Cortical Bone Trajectory(CBT) Screw Fixation System is modular, with the screw assembled intraoperatively, posterior spinal fixation system and less invasive surgery. The CBT Screw Fixation System allows surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The CBT Screw Fixation 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 bone screws have self-tapping function in CBT Screw Fixation System. The double lead thread is applied to the all bone screws to shorten the operation time. CBT Screw Fixation 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)

Indications For Use:

The CBT Screw Fixation 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
- 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:

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

The mechanical performance of the CBT Screw Fixation 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 same indications for use
- Similar design features
- Incorporate the same materials
- The equivalent mechanical performance

2. Performance Testing

The CBT 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. All tests met all acceptance criteria and that verifies performance of the CBT Screw Fixation System is substantially equivalent to predicate devices.

The following tests were performed:

- (1) Static compression bending test according to ASTM F1717-15
- (2) Static torsion test according to ASTM F1717-15
- (3) Compression bending fatigue test according to ASTM F1717-15
- (4) Dissociation test

3. Conclusion

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