



September 10, 2018

U&I Corporation
Kwang-Eun Song
Regulatory Affairs Specialist
20, Sandan-ro 76beon-gil(Rd)
Uijeongbu-si, Gyeonggi-do 11781
KOREA

Re: K182055

Trade/Device Name: SECULOK™ ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 27, 2018
Received: August 2, 2018

Dear Mr. Song:

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)

K182055

Device Name

SECULOK™ ACP System

Indications for Use (Describe)

The SECULOK™ ACP System is intended for anterior vertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- ☐ Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration disc confirmed by patient history and radiographic studies);
- ☐ Spondylolisthesis
- ☐ Trauma (including fractures, dislocation)
- ☐ Spinal stenosis
- ☐ Tumors
- ☐ Deformity (defined as scoliosis, kyphosis, or lordosis)
- ☐ Pseudoarthrosis
- ☐ Failed previous fusion

WARNING: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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: Kwang-Eun Song, Regulatory Affairs Specialist
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Date Prepared: July 27, 2018

Device Name: Trade Name: SECULOK™ ACP System

Classification Name: Spinal Intervertebral Body Fixation Orthosis

Common Name: Anterior Cervical Plate

Product Code: KWQ

Predicate Devices: ASPIRON™ ACP System (K131200, K140234)

Description of Device:

The SECULOK™ ACP System consists of a variety of shapes and sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. All implant components are made from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136. All implants are single use only.

Indications For Use:

The SECULOK™ ACP System is intended for anterior vertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration disc confirmed by patient history and radiographic studies);
- Spondylolisthesis
- Trauma (including fractures, dislocation)
- Spinal stenosis
- Tumors
- Deformity (defined as scoliosis, kyphosis, or lordosis)
- Pseudoarthrosis
- Failed previous fusion

WARNING: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Substantial Equivalence:

SECULOK™ ACP System is substantially equivalent to ASPIRON™ ACP System (K131200, K140234) in design, material, mechanical performance, function and intended use.

The mechanical performance of the SECULOK™ ACP 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 materials
- The equivalent mechanical performance

2. Performance Testing

The SECULOK™ ACP 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 SECULOK™ ACP System is substantially equivalent to predicate devices.

The following tests were performed:

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

3. Conclusion

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