October 23, 2020

Wiltrom Corporation Limited
Freda Lin
RA Specialist
1F., No. 26, Sec. 2, Shengyi Rd.
Zhubei City, Hsinchu 30261
Taiwan

Re: K202894
Trade/Device Name: Wiltrom Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: September 24, 2020
Received: September 28, 2020

Dear Freda Lin:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K202894

Device Name
Wiltrom Spinal Fixation System

Indications for Use *(Describe)*
The Wiltrom Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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

I. Submitter	Wiltrom Corporation Limited 1F, No. 26, Sec. 2, Shengyi Rd. Zhubei City, Hsinchu County 30261 Taiwan
Contact Information	Freda Lin, RA Specialist 1F, No. 26, Sec. 2, Shengyi Rd. Zhubei City, Hsinchu County 30261 Taiwan TEL: +886-3-6107168 FAX: +886-3-6580006
Date Prepared	Sep 24, 2020
II. Subject Device	Wiltrom Spinal Fixation System
Common Name	Pedicle Screw System
Classification Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	21 CFR §888.3070
Product Code / Device Class	NKB / Class II
510(k) Review Panel	Orthopedic
III. Predicate Device	Wiltrom Spinal Fixation System (K172548)

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IV. Device Description

The Wiltrom Spinal Fixation System is comprised of screws, rods, cross-link connector and associated surgical instruments that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The Wiltrom Spinal Fixation System is designed to be used to stabilize the vertebrae through a posterior approach. The Wiltrom spinal implants are made of Ti-6Al-4V ELI material which complies with ISO 5832-3 and ASTM F136. Wiltrom Spinal Fixation System is provided non-sterile, and the implants are for single use only.

V. Indication for Use

The Wiltrom Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

VI. Comparison of Technological Characteristics

The submission is to update the surgical instruments of the existing device cleared under K172548 to make the classification of the instruments clear and also seek clearance for three device-specific instruments. The material of implants, implant dimensions, principle of operation, and surgical approach are identical to the cleared device.

VII. Performance Data

In accordance with ASTM F1717-15, mechanical testing including static torsion testing, static and dynamic axial compression bending testing were conducted to evaluate the safety and effectiveness of the Wiltrom Spinal Fixation System. The performance of Wiltrom spinal implants in stabilizing the operative site and the mechanical safety was demonstrated, which is not affected by the proposed changes. Therefore, no other performance data is necessary to support substantial equivalence.

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VIII. Conclusion

Wiltrom Spinal Fixation System is substantially equivalent to the predicate device in regards to intended use, indications for use, and technological characteristics. Furthermore, the mechanical testing and other supporting information sufficiently demonstrate that Wiltrom Spinal Fixation System is as safe, as effective, and performs as well as the legally marketed predicate device.