August 12, 2019

Baui Biotech Co., Ltd.
Mr. Herman Jhan
Regulatory Affairs Supervisor
6F., No. 8, Sec. 1, Zhongxing Rd., Wugu Dist.
24872 New Taipei City
Taiwan (R.O.C.)

Re: K191494
Trade/Device Name: Facilis™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: July 30, 2019
Received: July 31, 2019

Dear Mr. Jhan:

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,

Ronald P. Jean, Ph.D.
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)*
K191494

Device Name
Facilis™ Spinal System

Indications for Use *(Describe)*
The Facilis™ Spinal System is intended for posterior, non-cervical fixation 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: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion. The Facilis™ Spinal System is to be used with autograft and/or allograft.

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.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. §807.92.

Preparation Date: May 28, 2019

Applicant/Sponsor: BAUI BIOTECH CO., LTD.
6F., No.8, Sec.1, Zhongxing Rd., Wugu Dist., 24872
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Contact Person: Herman Jhan
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Proprietary Name: Facilis™ Spinal System

Common Name: Pedicle Screw System
Non-pedicle spinal fixation system

Classification Name: Thoracolumbosacral pedicle screw system (21 CFR 888.3070)

Classification Identification: Class II
Product codes: NKB, KWP

Predicate Device: Facilis™ Spinal System (K161231)

Device Description:
The Facilis™ Spinal System is a system that is indicated for multiple types of spinal fusion procedures (please see Section IV). All components are made from titanium alloy Titanium-6 Aluminum-4 Vanadium (Ti-6AL-4V), a biocompatible

material which complies with ASTM F136. The components, which are included as part of the system, include screws, rods, hooks and accessory connection components. The Facilis™ Spinal Systems are supplied "Non-Steriled" and must be sterilized before use.
The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

Indications for Use:
The Facilis™ Spinal System is intended for posterior, non-cervical fixation 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: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); spinal tumor; pseudoarthrosis; and failed previous fusion. The Facilis™ Spinal System is to be used with autograft and/or allograft.

Substantial Equivalence:

A. Predicate device name: Facilis™ Spinal System
B. Predicate K number: K161231
C. Comparison with predicate:

Added two kinds screw to Facilis™ Spinal System：cannulated poly axial screw, pedicle long screw, and one transverse link and inside hex locking screw. Facilis™ Spinal System added new components, has the following similarities to the predicate device:

- Same operating principle
- Same fundamental scientific technology
- Incorporate the same materials
- Same shelf life
- Packaged using the same materials
- Manufactured by the same process

The modifications encompass:

- Addition of screws type
- Addition of transverse link type
- Addition of inside hex locking screw

Performance Characteristics:

The mechanical testing performed for the subject Facilis Spinal System with its components and the predicate devices is in accordance with ASTM F1717 and ASTM F1798. Specifically, compression bending, fatigue bending, and static torsion of the subject and the predicate systems were tested. All testing results passed acceptance criteria and are equivalent to predicate devices.

2. Conclusion:
   Based on the information provided in this submission, the Facilis™ Spinal System is substantially equivalent to the predicate Facilis™ Spinal System.