DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 23, 2017

BAUI BIOTECH CO., LTD.
Mr. Herman Jhan
Regulatory Affairs Specialist
6F, No.8, Sec.1, Zhongxing Road, Wugu Dist.
24872 New Taipei City
Taiwan (R.O.C.)

Re: K161231
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: December 20, 2016
Received: December 22, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

IV. INDICATION FOR USE STATEMENT

510(k) Number: K161231

Device Name: Facilis™ Spinal System

Indications For Use:

The Facilis™ Spinal System is a non- cervical, pedicle screw system intended to provide posterior, non-cervical 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 spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

The Facilis™ Spinal System is also indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the implant fixed or attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Prescription Use_____V_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

V. 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: January 12, 2017

Applicant/Sponsor: BAUI BIOTECH CO., LTD.
6F., No.8, Sec.1, Zhongxing Rd., Wugu Dist., 24872 New Taipei City, Taiwan(R.O.C.)

Contact Person: Herman Jhan
Phone: +886-2-8976-9538 #154
Fax: +886-2-8976-9608
Email: ra.bu@baui.com.tw

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) and Spinal interlaminal fixation orthosis (21 CFR 888.3050)

Classification Identification: Class II
Product codes: NKB, KWP

Primary Predicate Device: CD HORIZON® Spinal System (K981676)

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.

Indications for Use:

The Facilis™ Spinal System is a non-cervical, pedicle screw system intended to provide posterior, non-cervical 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 spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

The Facilis™ Spinal System is also indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, with the implant fixed or attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Substantial Equivalence:

The Facilis™ Spinal System is substantially equivalent to the CD HORIZON® Spinal Systems, the predicate legally marketed device (K981676). The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the listed predicate device.

Testing was performed to support the equivalence of the proposed pedicle screw system in accordance with FDA Guidance "Guidance for Industry and FDA Staff: Spinal Systems 510(k)s." The following testing was performed in accordance with ASTM F1717: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model with particular requests in Static Compression Bending, Static Torsion and Dynamic Compression Bending.