June 11, 2019

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

Re: K182416
Trade/Device Name: NOVA Minimally Invasive System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: May 13, 2019
Received: May 16, 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,

for Raquel Peat, PhD, MPH, USPHS
Director
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)*
K182416

Device Name
NOVA Minimally Invasive System

Indications for Use *(Describe)*
The NOVA Minimally Invasive 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:
1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies),
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation)
4. Spinal stenosis,
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previouis 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.

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510(k) SUMMARY

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

Preparation Date: June 6, 2019

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: NOVA Minimally Invasive System

Common Name: Pedicle Screw Fixation System

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

Classification Identification: Class II
Product code: NKB

Primary Predicate Device: Firebird Spinal Fixation System (K171082)

Device Description:
The NOVA Minimally Invasive System consists of cannulated polyaxial screws, straight and pre-bent rods, and set screws. The components are manufactured from titanium alloy per ASTM F136. The screws range in diameter from 5.5 mm to 7.0 mm and in length from 20 mm to 70 mm. The implants are not compatible with components or metal from any other manufacturer's system. The NOVA

Minimally Invasive System can be used for both percutaneous and mini-open surgery.

Indications for Use:

The NOVA Minimally Invasive 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:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation),
4. Spinal stenosis,
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

Substantial Equivalence:

The NOVA Minimally Invasive System is substantially equivalent to the predicate device listed above based on intended use, materials, designs, and operational principles.

Performance Testing:

The following tests were performed on the subject components per ASTM F1717: static compression bending, static torsion, and dynamic compression bending. Results of these mechanical tests demonstrate substantially equivalent mechanical performance to predicate devices.

Conclusion:

The NOVA Minimally Invasive System is substantially equivalent to predicate devices with respect to intended use, materials, technological characteristics, and mechanical performance.