October 17, 2024

BAUI Biotech Co., Ltd.
Herman Jhan
Regulatory Affairs Asst. Manager
6F., No.6, Sec.1, Zhongxing Rd., Wugu Dist.
New Taipei City, 24872
Taiwan

Re: K242899
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: August 30, 2024
Received: September 23, 2024

Dear Herman 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242899

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 previous 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: August 30, 2024

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
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Email: herman@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 codes: NKB

Primary Predicate Device: NOVA Minimally Invasive System (K182416)

Device Description:
The NOVA Minimally Invasive System consists of cannulated polyaxial screw, 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:

A. Predicate device name: NOVA Minimally Invasive System
B. Predicate K number: K182416
C. Comparison with predicate:

Modified reference number in labeling, including IFU and labels.

Package labels and insert information hasn't been changed for this modification, the indication is the same as predicate device. It has the following similarities to 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:

- Modified reference number
- Labeling change due to above modifications

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

Performance Characteristics:

The mechanical testing performed for the subject NOVA Minimally Invasive System with its components and the predicate devices is in accordance with ASTM F1717. There are no design change are involved for the design verification tests. The performance data for design control activities are unnecessary this time.

Conclusion:

Based on the information provided in this submission, the NOVA Minimally Invasive System is substantially equivalent to the predicate NOVA Minimally Invasive System.

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