Narang Medical LTD.
Vivek Narang
Director
Narang Tower, 46, Community Center, Naraina, Phase -1
Delhi, New Delhi 110028
India

February 20, 2024

Re: K233150
Trade/Device Name: NET BRAND Osteosynthesis Nailing System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDS, HSB, HWC, HTY
Dated: January 16, 2024
Received: January 16, 2024

Dear Vivek Narang:

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.

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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.02.20 11:32:39 -05'00'

for: Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233150

Device Name
NET BRAND Osteosynthesis Nailing System

Indications for Use *(Describe)*
NET BRAND Osteosynthesis Nailing System are provided non-sterile.

Tibial Nails are indicated for stabilization of fractures of proximal and distal tibia, tibial shaft, open and closed tibial shaft fractures, certain pre and postisthmic fractures, non-unions and malunions.

Femoral Nails are indicated for stabilization of femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

The Elastic Nails are indicated for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or the flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in paediatric or small statured patients. In paediatric applications, the flexibility of the elastic intramedullary nailing allows it to be inserted at a point which avoids disruption of the bone growth plate.
All Implants are for single use only.

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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NARANG MEDICAL LTD.

Premarket Notification 510(k) Summary as required by Section 807.92

General Company Information as required by 807:92 (a)

(a.1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared.

Submitter's Name:	NARANG MEDICAL LTD.
Address:	**Office:** Narang Tower,46, Community Center, Naraina, Phase -1, New Delhi-110028, India. **Factory**: Plot Number: D-4, Sector A-2 Tronica City, Loni, Ghaziabad, Uttar Pradesh, 201102 India
Contact Person Name:	Vivek Narang
Title:	Director
Phone Number:	+91 11 45554000, +91 9810738300
Dated:	21-09-2023

This is a bundled submission.

Throughout the submission there is a mention of NET BRAND Osteosynthesis Nailing System that represents the range of products covered under this 510(k) submission.

a.2: The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:

- NET BRAND Osteosynthesis Nailing System

Common or Usual Name:

- Orthopaedic Bone Nail
- Orthopaedic Bone Screw

Classification Name:

- Intramedullary fixation rod
- Smooth or threaded metallic bone fixation fastener
- Single/multiple component metallic bone fixation appliances and accessories

Product Code:

JDS, HSB, HWC, HTY

Device Class: II

Review Name: Orthopaedic

Regulation Number: 21 CFR 888.3020, 21 CFR 888.3030 and 21 CFR 888.3040

Variants/Types:

NET BRAND Osteosynthesis Nailing System are further subdivided into following categories

S. No.	Category	Types
01	Tibia Nail	Cannulated, Unreamed and Universsal Long Bend Type
02	Femoral Nail	Cannulated Long, Cannulated Short, Antirotation Long, Antirotation Short
03	Elastic Nail	Diameters: 2.0, 2.5, 3.0, 3.5, 4.0mm (Length 440mm)
04	Bone Screws	Ø4.8mm Cancellous Locking Screw (Dual Core) Locking screws for Perfect Tibial Nails, 4.35mm and 4.8mm" Hip Screws, Ø6.35mm for Perfect Femoral Nail Locking Bolt, Ø4.5mm (Self Tapping) Locking Bolt, Ø 6.0mm (Self Tapping) Locking Bolt, Ø 4.9 mm (Self Tapping) PFNA-II Nail Blade Screw (Cannulated)

NARANG MEDICAL LTD.

Further Description of NET BRAND Osteosynthesis Nailing System.

Generally there are following types of Bone Nail used with Locking Screws and Locking Bolts. These Bone Nails are generally designed on the basis of the bone Tibia and Femur.

S. No.	Category	Types
01	Tibia Nail	Perfect Tibial Nails – Cannulated, Multi-Fix Tibial Nail - Cannulated (Dynamic Hole), Multi-Fix Tibial Nail - Unreamed (Dynamic Hole) Easy Universal Tibial Nail Long Bend - Standard Distal Holes
02	Femoral Nail	Perfect Femoral Nail - Cannulated (Long) for Right and Left Leg Perfect Femoral Nail - Cannulated (Short) PFNA-II. Proximal Femoral Nail, Antirotation – Short PFNA-II. Proximal Femoral Nail, Antirotation - Long (Left/Right)
03	Elastic Nail	Ø2.0mm x Length 44cm Ø2.5mm x Length 44cm Ø3.0mm x Length 44cm Ø3.5mm x Length 44cm Ø4.0mm x Length 44cm
04	Screws and Locking Bolts	Ø4.8mm Cancellous Locking Screw (Dual Core) for Perfect Tibial Nails Locking Screws, Ø4.8mm for Perfect Tibial Nails Locking Screws, Ø4.35mm for Perfect Tibial Nails Hip Screws, Ø6.35mm for Perfect Femoral Nails Locking Bolt, Ø4.5mm (Self Tapping) for Multi-Fix Nail Locking Bolt, Ø 6.0mm (Self Tapping) for Multi-Fix Nail PFNA-II Nail Locking Bolt, Ø 4.9 mm (Self Tapping) PFNA-II Nail Blade Screw (Cannulated)

A3) Identification of the Predicate Device:

Following are the predicate device 510(k) with which we are declaring substantial equivalence:

Following is the range of variants covered with their corresponding predicate devices.

S. No.	Subject Device	Corresponding Locking Screws and End Caps	Predicate Device
1.	Perfect Tibial Nails – Cannulated	Ø4.8mm Cancellous Locking Screw (Dual Core) for Perfect Tibial Nails Locking Screw, Ø4.35mm for Perfect Tibial Nails Locking Screws, Ø4.8mm for Perfect Tibial Nails	SYNTHES Titanium Tibia Nail (K914453)
2.	Multi-Fix Tibial Nail - Cannulated (Dynamic Hole)	Locking Bolt, Ø4.5mm (Self Tapping) for Multi-Fix Nail Locking Bolt, Ø 6mm (Self Tapping) for Multi-Fix Nail	SYNTHES Titanium Tibia Nail (K962047)
3.	Multi-Fix Tibial Nail - Unreamed (Dynamic Hole)	Locking Bolt, Ø4.5mm (Self Tapping) for Multi-Fix Nail Locking Bolt, Ø 6mm (Self Tapping) for Multi-Fix Nail	SYNTHES Titanium Tibia Nail (K914453)
4.	Easy Universal Tibial Nail Long Bend - Standard Distal Holes	Ø4.8mm Cancellous Locking Screw (Dual Core) for Perfect Tibial Nails Locking Screw, Ø4.35mm for Perfect Tibial Nails Locking Screws, Ø4.8mm for Perfect Tibial Nails	SYNTHES (USA) UNIVERSAL TIBIAL NAIL AND UNREAMED TIBIAL NAIL (K914453)
5.	Perfect Femoral Nail - Cannulated (Long) for Right and Left Leg	Locking Bolt 6.0mm (Self Tapping) Locking Bolt 4.9mm (Self Tapping) Hip Screws, Ø6.35mm for Perfect Femoral Nails	SYNTHES Lateral Entry Femoral Nail (K040336)
6.	Perfect Femoral Nail - Cannulated (Short)	Locking Bolt 6.0mm (Self Tapping) Locking Bolt 4.9mm (Self Tapping) Hip Screws, Ø6.35mm for Perfect Femoral Nails	SYNTHES Cannulated Femoral Nail (K954856)
7.	PFNA-II. Proximal Femoral Nail, Antirotation – Short	PFNA-II Nail Locking Bolt, Ø 4.9 mm (Self Tapping) PFNA-II Nail Blade Screw (Cannulated)	SYNTHES TROCHANTERIC FIXATION NAIL (TFN) SYSTEM (K011857 & K070294)

8.	PFNA-II. Proximal Femoral Nail, Antirotation - Long (Left/Right)	PFNA-II Nail Locking Bolt, Ø 4.9 mm (Self Tapping) PFNA-II Nail Blade Screw (Cannulated)	SYNTHES TROCHANTERIC FIXATION NAIL (TFN) SYSTEM (K011857)
9.	Elastic Nail	Not Applicable	Synthes Elastic Intramedullary nailing System (K971783) and Depuy Ace Nancy Nail (K032687)
10.	Ø4.8mm Cancellous Locking Screw (Dual Core) for Perfect Tibial Nails	Not Applicable	SYNTHES Titanium Tibia Nail (K914453)
11.	Locking Screw, Ø4.35mm for Perfect Tibial Nails	Not Applicable	SYNTHES Titanium Tibia Nail (K914453)
12.	Locking Screws, Ø4.8mm for Perfect Tibial Nails	Not Applicable	SYNTHES Titanium Tibia Nail (K914453)
13.	Hip Screws, Ø6.35mm for Perfect Femoral Nails	Not Applicable	SYNTHES Titanium Tibia Nail (K914453)
14.	Locking Bolt, Ø4.5mm (Self Tapping) for Multi-Fix Nail	Not Applicable	SYNTHES Titanium Tibia Nail (K962047)
15.	Locking Bolt, Ø 6mm (Self Tapping) for Multi-Fix Nail	Not Applicable	SYNTHES Titanium Tibia Nail (K962047)
16.	PFNA-II Nail Locking Bolt, Ø 4.9 mm (Self Tapping)	Not Applicable	SYNTHES TROCHANTERIC FIXATION NAIL (TFN) SYSTEM (K011857)
17.	PFNA-II Nail Blade Screw (Cannulated)	Not Applicable	SYNTHES TROCHANTERIC FIXATION NAIL (TFN) SYSTEM (K011857) & K070294

a4). A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device

Device Description:

NET BRAND Osteosynthesis Nailing System consists of various shape and sizes of Nails and Screws, Locking Bolts.

The NET BRAND Osteosynthesis Nailing System are fabricated from Stainless Steel And Titanium.

The system contains several models based on the size of the device and application site such as fixation/reconstruction of Tibia and Femoral bones appropriate for the size of the device. The Nail implants are available in many diameters and lengths.

These all are mainly divided into

- Tibia Nail
- Femoral Nail
- Elastic Nail
- Corresponding Screws and Locking Bolts for Fixations of These Nails.

S. No.	Type of Device	Range of Diameter	Range of Length
01.	Perfect Tibial Nails – Cannulated	08mm to 13mm	255mm to 465mm
02.	Multi-Fix Tibial Nail - Cannulated (Dynamic Hole)	09mm to 13mm	260mm to 430mm
03.	Multi-Fix Tibial Nail - Unreamed (Dynamic Hole)	08mm to 9mm	260mm to 440mm
04.	Easy Universal Tibial Nail Long Bend - Standard Distal Holes	09mm to 12mm	270mm to 380mm
05.	Perfect Femoral Nail - Cannulated (Long) for Right and Left Leg	09mm to 13mm	320mm to 480mm
06.	Perfect Femoral Nail - Cannulated (Short)	09mm to 13mm	180mm to 240mm
07.	PFNA-II. Proximal Femoral Nail, Antirotation – Short 125degree and 130 degree	09mm to 12mm	170mm to 240mm
08.	PFNA-II. Proximal Femoral Nail, Antirotation - Long (Left/Right) 125° and 130°	09mm to 10mm	260mm to 420mm
09.	Elastic Nail	Diameters: 2.0, 2.5, 3.0, 3.5, 4.0mm	440mm
10.	Ø4.8mm Cancellous Locking Screw (Dual Core) for Perfect Tibial Nails	Ø4.8mm	25mm to 80mm
11.	Locking Screw, Ø4.35mm for Perfect Tibial Nails	Ø4.35mm	18mm to 80mm
12.	Locking Screws, Ø4.8mm for Perfect Tibial Nails	Ø4.8mm	26mm to 85mm
13.	Hip Screws, Ø6.35mm for Perfect Femoral Nails	Ø6.35mm	60mm to 115mm
14.	Locking Bolt, Ø4.5mm (Self Tapping) for Multi-Fix Nail	Ø4.5mm	26mm to 80mm
15.	Locking Bolt, Ø 6.0mm (Self Tapping) for Multi-Fix Nail	Ø6.0mm	30mm to 90mm
16.	PFNA-II Nail Locking Bolt, Ø 4.9 mm (Self Tapping)	Ø4.9mm	24mm to 100mm
17.	PFNA-II Nail Blade Screw (Cannulated)	12.0mm	75mm to 120mm

These implants are supplied non-sterile, the products have to be sterilized prior to use.

A5). A statement of the intended use of the device

Indications for Use:

• NET BRAND Osteosynthesis Nailing System are provided non-sterile.

Tibial Nails are indicated for stabilization of fractures of proximal and distal tibia, tibial shaft, open and closed tibial shaft fractures, certain pre and postisthmic fractures, non-unions and malunions.

Femoral Nails are indicated for stabilization of femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

The Elastic Nails are indicated for fixation of diaphyseal fractures of the long bones where the medullary canal is narrow or the flexibility of the implant is paramount. This includes upper extremity fractures in all patients and lower extremity fractures in paediatric or small statured patients. In paediatric applications, the flexibility of the elastic intramedullary nailing allows it to be inserted at a point which avoids disruption of the bone growth plate.
All Implants are for single use only.

a6). Summary of Technological Characteristics as compared to the predicate devices:

Substantial equivalence including comparison with predicate devices

A comparison between the NET BRAND Osteosynthesis Nailing System and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Following is the summary of parameters in which the comparison has been verified:

S. No.	**Characteristics**	Predicate Device Versus Subject Device **(**NET Brand**)**	**Remarks**
01	Indications for use	Similar intended use in Subject Device and Predicate device	Equivalent
02	Material	Same material used in Subject Device and Predicate device	Equivalent
03	Performance Standards	Same performance standards used in both Subject Device as well as predicate device	Equivalent
04	Sterilization	Same method of sterilization used in both Subject Device as well as Predicate device	Equivalent
05	Dimensional Verification	Similar dimensions found in both Subject Device as well as Predicate device	Equivalent

b1). Discussion on the non-clinical testing performed

Following are the applicable product standards considered for non-clinical standards

A: Material Standards

B: Performance Standards

A: Material Standards:

The material standards are the essential part to be complied to first, as it is the basis of manufacturing metallic surgical implants.

We have complied to following material standards

1. ASTM F 136: Standard specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.

2. ASTM F 139: Standard Specification for Wrought 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants

B: Performance Standards:

The device performance of NET BRAND Osteosynthesis Nailing System has been demonstrated against following applicable standards

For Bone Nail:

As per ASTM F 1264
Static Four Point Bend Test: Side-by-Side testing was performed
Static Torsional Properties: Side-by-Side testing was performed
Bending Fatigue Properties: Side-by-Side testing was performed
and
ASTM F 384
Static Compression Bend Test: Side-by-Side testing was performed
Bending Fatigue Properties; Side-by-Side testing was performed

For Bone Screws:

As per ASTM F 543 :Torsional Properties: Side-by-Side testing was performed, Driving Torque : Side-by-Side testing was performed, Pull-out Test: Side-by-Side testing was performed.

b2). Discussion on the clinical evaluation referenced and relied upon:

NET BRAND Osteosynthesis Nailing System are of similar design and pattern as well as same intended use. Clinical information was not necessary to demonstrate substantial equivalence.

CONCLUSION:

General, Safety and Performance conclusion:

From the available data available we can justify that the NET BRAND Osteosynthesis Nailing System are as safe, and effective and perform as same indications for use as that of already marketed predicate devices identified in Section A3 of this 510(k) Summary.