DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 24, 2017

Narang Medical USA Corporation
Mr. Reginald Swift
Quality/Regulatory Director
15951 SW 41 St
Suite 800b
Davie, FL 33331

Re: K163425
Trade/Device Name: NMUC Brand Small And Large Fragment Osteosynthesis Plating System, NMUC Brand of DHS/DCS Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 24, 2017
Received: February 24, 2017

Dear Mr. Swift:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163425

Device Name
NMUC Brand Small And Large Fragment Osteosynthesis Plating System, NMUC Brand of DHS/DCS Plating System

Indications for Use *(Describe)*
NMUC Brand Small and Large Fragment Osteosynthesis System is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, distal femur, proximal tibia, tibial pilon, fibula, pelvis and acetabulum fractures; periprosthetic fractures; The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone. This system is not indicated for use in the spine.

NMUC Brand DHS/DCS plating system may be used for fixation of the fractures of proximal femur such as femoral neck, trochanteric, pertrochanteric or intertrochanteric zones. The system is indicated for use in adult patients only. 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 USA CORPORATION

510(k) Summary

Date : 1/25/17

Registration Number: 3012544669

Submitted by: Narang Medical USA Corporation
15951 SW 41 St Suite 800b
Davie, FL 33331

Contact Person: Reginald Swift
Quality/Regulatory Director
Narang Medical USA Corporation
reggie@narang.com

510(k) Number: K163425

This is a bundled submission that includes devices that are used for the same orthopedic region(s).

Primary Predicate: K150561

Proprietary Name(s):

- NMUC Brand Small and Large Fragment Osteosynthesis Plating System
- NMUC Brand of DHS/DCS Plating System

Common Name:

- Orthopedic Bone Plates
- Orthopedic Bone Screws

Classification & Product Code References:

- Class II
- HRS – Plate, Fixation, Bone (21 CFR 888.3030)
- HWC – Screw, Fixation, Bone (21 CFR 888.3040)

Device Description:

NMUC brand small fragment and large fragment Osteosynthesis plating system consists of plates and screws in a variety of designs and made from Ti-6Al-4V (Titanium) alloy or stainless steel. Plates are provided in a straight design also in various geometric configurations that are commonly used in trauma and reconstructive surgery. Plates are provided with screw holes to accommodate non-locking and locking screw designs. Screws are provided in, 3.5mm cortex self-tapping, 4.5 mm diameter cortex self-tapping and 2.7mm diameter self-tapping cortex locking, 3.5mm self-tapping cortex locking, 5.0mm cortex locking thread designs in various lengths.

DHS/DCS, systems are made from Ti-6Al-4V (Titanium) alloy or stainless steel and consists of DHS/DCS plates, lag screws, compression screws and 4.5mm diameter cortex screw self-tapping. The plates are available with barrel length 25mm and 38 mm with angles variances between 130° to 150°. The DCS plate have angles of 95°.

The products are provided NON-STERILE only. Subsequent of being sold as NON-STERILE product, the intention is to achieve sterility by utilizing autoclaving method on parameters of $SAL10^{-6}$ AAMI ST79 & ISO 17665-1.

Intended / Indications for Use:

NMUC Brand Small Fragment and Large Fragment Osteosynthesis System is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, distal femur, proximal tibia, tibial pilon, fibula, pelvis and acetabulum fractures; periprosthetic fractures; The use of locking plate/screw systems is suited for treatment of fractures in osteopenic bone. This system is not indicated for use in the spine.

NMUC Brand DHS/DCS plating system may be used for fixation of the fractures of proximal femur such as femoral neck, trochanteric, pertrochanteric or intertrochanteric zones. The system is indicated for use in adult patients only. All implants are for single use only

Technological Characteristics:

Equivalence is concretely supported in its comparison as being the exact same device as noted in the substantial equivalence portion of this document and cleared under cited 510(k) clearance. Comparison between noted devices and predicates are exactly the same under all regards in its *intended use, packaging, labeling, materials and design* of the product.

Substantial Equivalence:

- The components and assemblies of this device are substantially equivalent to the following:

510(k) Number	Company	Product	Reference to (Company Product)
K150561	Narang Medical Ltd	NET brand Small and large fragment Osteosynthesis family plating system	NMUC branded small and large Osteosynthesis family system
K150561	Narang Medical Ltd.	NET brand DHS/DCS family plating system	NMUC branded DHS/DCS family plating system

- Equivalence is based on similarities in intended use, materials and design to the predicate devices demonstrating substantial equivalence to the predicate devices
- Prior submission related to devices substantial equivalence (exclusive to products examined under submission) summary has been based from **510(k) number: K150561** under Narang Medical Limited in which is the manufacturer of the devices for Narang Medical USA Corporation.
    - **Legally marketed statement**: all devices that belong to the families of devices contained within both system of devices are legally marketed as Narang Medical Limited company devices (proved under submission K150561). All critical features including: intended surgical use, safety and efficacy, and technical features of the devices remain unchanged as only the labeling of the devices shall now only correspond to Narang Medical USA corporation as the company to legally market these family of devices (under submission K163425).

Performance Data:

All devices stated herein undergo the same manufacturing, testing and qualification methods as the predicate devices. Related specifications and standards in which device were tested to are below:

1. **ASTM F136 – Standard specification for wrought titanium**
2. **ASTM F138 – Standard specification for wrought 18chromium-14nickel-2.5molybdenum stainless steel**
3. **ASTM F139 – Standard specification for wrought stainless steel sheet and strip for surgical implants**

The information included in this submission demonstrates substantial equivalence. No performance testing was included in this submission.