Narang Medical Limited
Mr. Vivek Narang
Director
46, Naraina Industrial Area, Phase-1
New Delhi 110028
India

Re: K150561
Trade/Device Name: NET Brand Small Fragment and Large Fragment Osteosynthesis
Plating System, NET 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: September 22, 2015
Received: September 29, 2015

Dear Mr. 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 (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](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](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](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
Indications for Use

K150561

Device Name
NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating System

Indications for Use (Describe)
NET 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.

NET 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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:
Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAS Staff@fda.hhs.gov

“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.”
Premarket Notification 510(k) Summary As required by Section 807.92

General Company Information as required by 807:92 (a) (a.1)

Submitter’s Name : Narang Medical Limited

Address

Office : 46, Community Center, Naraina Industria Area, Phase-1, New Delhi 110028

Factory : Plot Number D-4, Sector A-2, Tronica City, Loni, Ghaziabad, 201102

CONTACT PERSON NAME : Mr. Vivek Narang

TITLE : Director

PHONE NUMBER : +91-45554000

Dated : 18-11-2015
This is a bundled submission.

Throughout the submission there is a mention of NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating 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 Small Fragment and Large Fragment Osteosynthesis Plating System,

NET Brand of DHS/DCS Plating System

**Common or Usual Name:**

Orthopaedic Bone Plates

Orthopaedic Bone Screws

**Classification Name:**

PLATES, FIXATION, BONE

SCREWS, FIXATION, BONE

**Product Code:**

HRS, HWC

**Device Class:**

II

**Review Panel:**

Orthopaedic

**Regulation Number:**

21 CFR 888.3030 and 21 CFR 888.3040
**Variants/Types:**

**NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System, **NET** Brand of DHS/DCS Plating System are further subdivided into following categories

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Category</th>
<th>Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Small Fragment Osteosynthesis Plating System</td>
<td>Locking</td>
</tr>
<tr>
<td>02</td>
<td>Large Fragment Osteosynthesis Plating System</td>
<td>Locking</td>
</tr>
<tr>
<td>03</td>
<td>DHS/DCS Plating System</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Further Description:**

**NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System consists of plates and screws in a variety of designs and sizes and made from Ti-6Al-4V alloy or stainless steel. Plates are provided in straight designs and 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 screws designs. Screws are provided in, 3.5mm Cortex Self-tapping, 4.5 mm Cortex self-tapping and 2.7mm self-tapping cortex locking, 3.5mm self-tapping Cortex Locking, 5.0 mm cortex Locking thread designs in various lengths. This system is not indicated for use in spine.

**NET** Brand of DHS/DCS Plating System made from Ti-6Al-4V alloy or stainless steel and consist of DHS/DCS Plates, lag Screw, compression screw, and 4.5 Cortex screw Self Tapping, The DHS plates are available with barrel length 25mm (short barrel) and 38mm (Standard barrel) and barrel angels varies in 130° to 150°. The DCS plate is having angle of 95°

The DHS/DCS Screw is available in total length from 50 to 145 mm, thread length 22mm, shaft diameter 7 mm and outer diameter of 12.5. The thread of DHS/DCS Screw has a buttress type.

The DHS/DCS Compression Screw can be used to achieve fracture compression. Its dimension is available with thread length 36mm and outer diameter 4.0 mm.
a3) IDENTIFICATION OF THE PREDICATE DEVICE:

For the purposes of US FDA's regulation of medical devices, NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating System are substantially equivalent in indications and design principles to the following predicate devices.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Device Name</th>
<th>510(k) Number</th>
<th>Predicate Manufacturer’s Name</th>
<th>Subject Device Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Synthes LCP Proximal Humerus Plate</td>
<td>K011815</td>
<td>Synthes (USA)</td>
<td>Filos - Proximal Humerus Safety Lock Plate 3.5 – Standard</td>
</tr>
<tr>
<td>2.</td>
<td>3.5 mm LCP Distal Humerus System</td>
<td>K033995</td>
<td>Synthes (USA)</td>
<td>Distal Humerus Safety Lock Plate 2.7/3.5, Dorsolateral</td>
</tr>
<tr>
<td>3.</td>
<td>3.5 mm LCP Distal Humerus System</td>
<td>K033995</td>
<td>Synthes (USA)</td>
<td>Distal Humerus Safety Lock Plate 2.7/3.5, Dorsolateral with Lateral Support</td>
</tr>
<tr>
<td>4.</td>
<td>3.5 mm LCP Distal Humerus System</td>
<td>K033995</td>
<td>Synthes (USA)</td>
<td>Medial Distal Humerus Safety Lock Plate 2.7/3.5mm</td>
</tr>
<tr>
<td>5.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>LC-DCP Safety Lock Plate 3.5</td>
</tr>
<tr>
<td>6.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>Safety Lock 'T' Plate 3.5, Right Angled</td>
</tr>
<tr>
<td>7.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>Safety Lock 'T' Plate 3.5, Oblique Angled</td>
</tr>
<tr>
<td>8.</td>
<td>Synthes Clavicle Hook Plate</td>
<td>K061753</td>
<td>Synthes (USA)</td>
<td>Clavicle Hook Safety Lock Plate 3.5</td>
</tr>
<tr>
<td>9.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>Reconstruction Safety Lock Plate 3.5 – Straight</td>
</tr>
<tr>
<td>10.</td>
<td>3.5 mm LCP Distal Humerus System</td>
<td>(K033995)</td>
<td>Synthes (USA)</td>
<td>Safety Lock Screw Ø 2.7mm - Self Tapping</td>
</tr>
<tr>
<td></td>
<td>Description</td>
<td>Code</td>
<td>Manufacturer</td>
<td>Details</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------------------------------------------------------</td>
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<td>----------------------------------------------</td>
</tr>
<tr>
<td>11.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>Safety Lock Screw Ø 3.5mm - Self Tapping</td>
</tr>
<tr>
<td>12.</td>
<td>Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications</td>
<td>K082807</td>
<td>Synthes (USA)</td>
<td>Broad LC-DCP Safety Lock Plate 4.5 /5.0</td>
</tr>
<tr>
<td>13.</td>
<td>Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications</td>
<td>K082807</td>
<td>Synthes (USA)</td>
<td>Narrow LC-DCP Safety Lock Plate 4.5/5.0</td>
</tr>
<tr>
<td>14.</td>
<td>Synthes (USA) LCP Proximal Femur Plate and Screws</td>
<td>K030858</td>
<td>Synthes (USA)</td>
<td>Proximal Femoral Safety Lock Plate 4.5/5.0/7.3</td>
</tr>
<tr>
<td>15.</td>
<td>Synthes LCP Distal Femur Plates</td>
<td>K062564</td>
<td>Synthes (USA)</td>
<td>Distal Femoral Safety Lock Plate 4.5/5.0</td>
</tr>
<tr>
<td>16.</td>
<td>Synthes LCP Proximal Tibia Plate</td>
<td>For Stainless Steel Plate (K011978)</td>
<td>Synthes (USA)</td>
<td>Proximal Lateral Tibial Safety Lock Plate 4.5/5.0</td>
</tr>
<tr>
<td></td>
<td>Synthes 4.5 mm Titanium LCP Proximal Tibia Plating System</td>
<td>For Titanium Plate K023802</td>
<td>Synthes (USA)</td>
<td></td>
</tr>
<tr>
<td>17.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>Safety Lock 'T' Plate 4.5/5.0</td>
</tr>
<tr>
<td>18.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>L Buttress Safety Lock Plate 4.5/5.0</td>
</tr>
<tr>
<td>19.</td>
<td>Synthes Small Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000684</td>
<td>Synthes (USA)</td>
<td>T Buttress Safety Lock Plate 4.5/5.0</td>
</tr>
<tr>
<td>20.</td>
<td>Synthes 4.5 mm LCP Straight Reconstruction Plates</td>
<td>K051986</td>
<td>Synthes (USA)</td>
<td>Reconstruction Safety Lock Plate 4.5/5.0</td>
</tr>
<tr>
<td>21.</td>
<td>Synthes Large Fragment Dynamic Compression Locking (DCL) System</td>
<td>K000682</td>
<td>Synthes (USA)</td>
<td>Safety Lock Screw Ø 5.0mm</td>
</tr>
</tbody>
</table>
These implants are sold non-sterile, the products have to be sterilized prior to use.

A5). (5) A statement of the intended use of the device

Indications for Use:

NET 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.
NET 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.

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

**SUBSTANTIAL EQUIVALENCE INCLUDING COMPARISON WITH PREDICATE DEVICES**

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics.

The subject and predicate devices encompass the same range of physical dimensions, are packaged using the same materials, and are to be sterilized by the same methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy. Performance data provided to demonstrate substantial equivalence included engineering analysis and mechanical testing according to ASIM F382, ASTM F 384 and ASTM F543.

Overall, Small Fragment and Large Fragment Osteosynthesis System of Narang Medical Limited have the following similarities to the predicate devices:

* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same or very similar materials, and
* has similar packaging and can be sterilized using the same materials and processes.

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Characteristics</th>
<th>Predicate Device Versus New Device (Auxein Brand)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Indications for use</td>
<td>Similar intended use in New Device and Predicate device</td>
<td>Equivalent</td>
</tr>
<tr>
<td>02</td>
<td>Material</td>
<td>Same material used in New Device and Predicate device</td>
<td>Equivalent</td>
</tr>
<tr>
<td>03</td>
<td>Performance Standards</td>
<td>Same performance standards used in both New Device as well as predicate device</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>
Sterilization
Same method of sterilization used in both New Device as well as Predicate device
Equivalent

Dimensional Verification
Same dimensions found in both New 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 raw material standards are the first standards to be complied, as it ensures compliance to the materials to be used for manufacturing of metallic surgical implants.

Following material standards have been adopted and complied:


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

B: Performance Standards:

The performance of NET Brand Small Fragment and Large Fragment Osteosynthesis Plating System, NET Brand of DHS/DCS Plating System has been verified as per the following standards

- ASTM F 382,
- ASTM F 384 and
- ASTM F 543
- For Bone Plates:

As per ASTM F 382 and ASTM F 384 Static Four Point Bend Test:
Conforms, Dynamic Four Point Bend Test: Conforms

- For Bone Screws:
As per ASTM F 543: Torsional Properties: Conforms, Driving Torque: Conforms, Pull-out Test: Conforms

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

**NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System,

**NET** Brand of DHS/DCS Plating System are of similar design and pattern as well as similar indications for use. Therefore Clinical information was not necessary to demonstrate substantial equivalence.

**CONCLUSION:**

General, Safety and Performance conclusion:

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parameter of Conclusion</th>
<th>Proposed Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Product Code</td>
<td>For Bone Plates: HRS</td>
<td>Same</td>
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<tr>
<td></td>
<td></td>
<td>For Bone Screws: HWC</td>
<td></td>
</tr>
<tr>
<td>02</td>
<td>Regulation Number</td>
<td>For Bone Plates: 21CFR 888.3030</td>
<td>Same</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For Bone Screws: 21CFR 888.3040</td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Regulatory Class</td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td>04</td>
<td>Indications For use</td>
<td>Same Indications For Use</td>
<td>Similar</td>
</tr>
<tr>
<td>05</td>
<td>Sterilization</td>
<td>Provided Non-Sterile and to be sterilized using Autoclaving Method to achieve SAL of $10^{-6}$ AAMI ST79, ISO 17665-1</td>
<td>Similar</td>
</tr>
<tr>
<td></td>
<td>Mechanical Test Performance</td>
<td>For Bone Plates:</td>
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<tr>
<td>06</td>
<td></td>
<td>As per ASTM F 382 and ASTM F 384</td>
<td>Same</td>
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<tr>
<td></td>
<td></td>
<td>- Static Four Point Bend Test Conforms</td>
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<td>- Dynamic Four Point Bend Test Conforms</td>
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<td>For Bone Screws:</td>
<td>As per ASTM F 543</td>
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<td>- Torsional Properties Conforms</td>
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<td>- Insertion Torque Conforms</td>
<td></td>
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<td></td>
<td></td>
<td>- Removal Torque Conforms</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>- Axial Pull-out Test Conforms</td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Material Standards</td>
<td>ASTM F 136, ASTM F 138 and ASTM F 139</td>
<td>Same</td>
</tr>
</tbody>
</table>

General, Safety and Performance Conclusion:

From the available data available we can justify that the **NET** Brand Small Fragment and Large Fragment Osteosynthesis Plating System, **NET** Brand of DHS/DCS Plating System are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in a3. Of 510(k) summary.

Therefore, our devices can be considered safe and effective for their intended use.