ADMINISTRATIVE INFORMATION
Manufacturer Name: NEOORTHO Produtos Ortopédicos S/A
Rua Ângelo Domingos Durigan 607, Cascatinha
82020-340 Curitiba - PR, Brazil
Telephone: +55 41 3535-1033
Fax: +55 41 3535-1018

Official Contact: Luciane Yumi Suzuki de Oliveira
NEOORTHO Produtos Ortopédicos S/A

Representative/Consultant: Kevin A. Thomas, PhD
Linda K. Schulz, BSDH, RDH
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130 USA
Telephone: +1 (858) 792-1235
Fax: +1 (858) 792-1236
Email: kthomas@paxmed.com
lschulz@paxmed.com

DEVICE NAME AND CLASSIFICATION
Trade/Proprietary Name: Small and Large Fragments Osteosynthesis System NEOFIX
Common Names: Plate, fixation, bone
Screw, fixation, bone
Classification Names: Single/multiple component metallic bone fixation appliances and accessories
Smooth or threaded metallic bone fixation fastener
Classification Regulations: 21 CFR 888.3030, Class II
21 CFR 888.3040, Class II
Product Codes: HRS
HWC
Classification Panel: Orthopedic Products Panel
Reviewing Branch: Orthopedic Devices Branch
INTENDED USE

Small and Large Fragments Osteosynthesis System NEOFIX is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, carpals, metacarpals, distal femur, proximal tibia, tibial pilon, fibula, calcaneus, tarsals and metatarsals; small fragments of the hand and wrist; pelvis and acetabulum fractures; periprosthetic fractures; metatarsal and phalangeal osteotomies; and carpal, metacarpal, wrist and ankle arthrodesis. 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.

DEVICE DESCRIPTION

NEOFIX consists of plates and screws in a variety of designs and sizes and made from commercially pure titanium or Ti-6Al-4V alloy. 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 cortical (locking and non-locking) and cancellous thread designs in various diameters and lengths.

EQUIVALENCE TO MARKETED DEVICE

NEOORTHO Produtos Ortopédicos S/A demonstrated that, for the purposes of FDA’s regulation of medical devices, Small and Large Fragments Osteosynthesis System NEOFIX is substantially equivalent in indications and design principles to the following predicate devices.

<table>
<thead>
<tr>
<th>Predicate Number</th>
<th>K Number</th>
<th>Company Name</th>
<th>Device Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>K012655</td>
<td>Acumed, Inc.</td>
<td>Congruent Bone Plate System</td>
</tr>
<tr>
<td>2</td>
<td>K071715</td>
<td>Acumed, Inc.</td>
<td>Acumed Congruent Bone Plate System</td>
</tr>
<tr>
<td>3</td>
<td>K041860</td>
<td>Synthes (USA)</td>
<td>Synthes (USA) LCP® Proximal Humerus Plates, long</td>
</tr>
<tr>
<td>4</td>
<td>K011815</td>
<td>Synthes (USA)</td>
<td>Synthes LCP Proximal Humerus Plates</td>
</tr>
<tr>
<td>5</td>
<td>K101421</td>
<td>DePuy Orthopaedics, Inc</td>
<td>DePuy Anatomic Locked Plating System Long Plate Line Extension</td>
</tr>
<tr>
<td>6</td>
<td>K000584</td>
<td>Synthes (USA)</td>
<td>Synthes (USA) Small Fragment Dynamic Compression Locking (DCL) System</td>
</tr>
<tr>
<td>7</td>
<td>K011335</td>
<td>Synthes (USA)</td>
<td>Synthes One-Third Tubular Plate</td>
</tr>
<tr>
<td>8</td>
<td>K000558</td>
<td>Synthes (USA)</td>
<td>Synthes (USA) Wrist Fusion Plates (WFP)</td>
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<td>9</td>
<td>K020401</td>
<td>Synthes (USA)</td>
<td>Synthes Calcaneal Plate</td>
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<tr>
<td>10</td>
<td>K020602</td>
<td>Synthes (USA)</td>
<td>Synthes Pilon Plate</td>
</tr>
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<td>11</td>
<td>K023802</td>
<td>Synthes (USA)</td>
<td>Synthes (USA) 4.5 mm Titanium LCP Proximal Tibia Plating System</td>
</tr>
<tr>
<td>12</td>
<td>K092609</td>
<td>Synthes (USA)</td>
<td>Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP)</td>
</tr>
<tr>
<td>13</td>
<td>K010766</td>
<td>Synthes (USA)</td>
<td>Synthes (USA) Large Fragment Locking Compression Plate (LCP) System-T Plate</td>
</tr>
<tr>
<td>14</td>
<td>K081353</td>
<td>Synthes (USA)</td>
<td>Synthes (USA) TomoFix™ Medial Distal Femur Plates</td>
</tr>
</tbody>
</table>
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 ASME F382 and ASTM F543.

Overall, Small and Large Fragments Osteosynthesis System NEOFIX has 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 is sterilized using the same materials and processes.
Dear Dr. Thomas:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/ReportaProbleni/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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number: K113733

Device Name: Internal Fixation System NEOFIX

Indications for Use:

Small and Large Fragments Osteosynthesis System NEOFIX is intended for small and large bone fracture fixation, arthrodesis and osteotomy fixation. Examples include: fractures of the clavicle, scapula, humerus, olecranon, radius, ulna, carpals, metacarpals, distal femur, proximal tibia, tibial pilon, fibula, calcaneus, tarsals and metatarsals; small fragments of the hand and wrist; pelvis and acetabulum fractures; periprosthetic fractures; metatarsal and phalangeal osteotomies; and carpal, metacarpal, wrist and ankle arthrodesis. 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.

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113733