510(K) Summary

FEB 24 2011

N.M.B. Medical Applications Ltd.

Piccolo Composite™ Plate System

Applicant Name

N.M.B. Medical Applications Ltd.

11 Ha'hoshlim St., Herzeliya 46724; Israel

Contact Person

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N.M.B. Medical Applications Ltd.

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Date Prepared

September 2010

Trade/Proprietary Name

Piccolo Composite™ Plate System

Common Name

Bone Plating System

Classification Name

Single/multiple component metallic bone fixation appliances and accessories; (21 CFR §888.3030; Class II; Product Code HRS).

Predicate Devices

Intended Use/Design/Technology/Operation

- Synthes 4.5 mm Locking Compression Plate System (Synthes; K082807)
- Synthes LCP Proximal Humerus Plate (Synthes; K011815)

- Synthes LCP Proximal Humerus Plate, Long (Synthes; K041860)
- DVR Anatomic Plating System (DePuy Orthopaedics, Inc. (previously Hand Innovations, Inc.); *e.g.*, K002775, K090374)

The above mentioned predicate plates are manufactured from titanium, titanium alloy and/or stainless steel.

Material

- Piccolo Composite™ Nailing System (formerly named Quantum IM Composite Nailing System) (N.M.B. Medical Applications Ltd.; K091425, K100497)
- Fixion® DHS System (N.M.B. Medical Applications Ltd.; K031401)

The material of the Piccolo Composite Plate (CFR-PEEK) was previously cleared for use in intramedullary rods (K091425, K100497).

Intended Use/Indications for Use

Piccolo Composite™ Diaphyseal Plate

The Piccolo Composite™ Diaphyseal Plate is indicated for the fixation of various long bones, such as the humerus, femur and tibia, including osteopenic bone, osteotomies, and nonunions or malunions in adult patients.

These plates are also indicated for fracture fixation of diaphyseal areas of long bones in pediatric patients.

Piccolo Composite™ Proximal Humerus Plate

The Piccolo Composite™ Proximal Humerus Plate is indicated for fractures, fracture dislocations, osteotomies, and nonunions of the proximal humerus, including in osteopenic bone.

Piccolo Composite™ Distal Volar Radius Plate

The Piccolo Composite™ Distal Volar Radius Plate is indicated for fractures and osteotomies of the distal volar radius.

System Description

The Piccolo Composite Plate System comprises implants (plates and screws/pegs), and a set of instruments.

The Plates are made of carbon fiber reinforced polyetheretherketone (CFR-PEEK), and are marked with a tantalum thread, to provide for their visualization under fluoroscopy. The following types of plates are available:

- Diaphyseal Plates (thickness: 4.5 mm or 5 mm);
- Proximal Humerus Plate (thickness: 3.7 mm);
- Distal Volar Radius Plate (thickness: 2.4 mm).

The Screws (and Pegs) are made of titanium alloy. Various screw types are available, such as cortical screws and locking screws, as well as pegs (to be used only with the Distal Radius Plate), in various dimensions.

Substantial Equivalence

The Piccolo Composite™ Plate System intended use, design, materials, technological characteristics, and principles of operation are substantially equivalent to those of the predicate devices, as applicable.

The Piccolo Composite Plates are manufactured from the identical CFR-PEEK material as the components cleared in K091425 and K100497.

Performance characteristics of the subject plates, such as single cycle (static) 4-point bending and dynamic (fatigue) 4-point bending were evaluated per ASTM F 382 – *Standard Specification and Test Method for Metallic Bone Plates*. Testing in support of the MR Conditional labeling parameters was also provided. Results were comparable to those of similar predicate devices, thus demonstrating that the system is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

N.M.B. Medical Applications Ltd.
% Ms. Hila Wachsler-Avrahami
Regulatory Affairs
11 Ha'hoshlim Street
Herzeliya 46724, Israel

FEB 2 4 2011

Re: K102597
Trade/Device Name: Piccolo Composite Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: HRS, KTT
Dated: January 7, 2011
Received: January 10, 2011

Dear Ms. Wachsler-Avrahami:

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/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 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,

For [illegible] Dep Dir

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 (if known): K102597

Device Name: **Piccolo Composite™ Plate System**

Indications for Use:

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Piccolo Composite™ Distal Volar Radius Plate

The Piccolo Composite™ Distal Volar Radius Plate is indicated for fractures and osteotomies of the distal volar radius.

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 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)

for M. Melkerson

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

510(k) Number K102597