K100497



# 510(K) Summary

## N.M.B. Medical Applications, Ltd.

## Piccolo Composite Nailing System

## (previously named the "Quantum IM Composite Nailing System")

JUN 21 2010

**Applicant Name**

N.M.B. Medical Applications, Ltd.
11 Ha'hoshlim St., Herzeliya 46724, Israel

**Contact Person**

Hila Wachsler-Avrahami
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11 Ha'hoshlim St., Herzliya 46724, Israel
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**Date Prepared**

February 2010

**Trade/Proprietary Name**

Piccolo Composite Nailing System (previously named the "Quantum IM Composite Nailing System")

**Common Name**

Intramedullary Nailing System

**Classification Name**

Rod, Fixation, Intramedullary and Accessories (21 CFR §888.3020; Product Code HSB)

**Predicate Devices**

- Quantum IM Composite Nailing System (N.M.B. Medical Applications, Ltd.; K091425);
- TriGen Straight Humeral Nail System (Smith & Nephew, Inc.; K032722);
- T2 Nailing System / T2 Proximal Humeral Nail (Howmedica Osteonics Corp.; K032523, K042396, K043404);

**Intended Use/Indications for Use**

Piccolo Composite Humeral and Proximal Humerus Nails

Indications for the Piccolo Composite Humeral Nail and Proximal Humerus Nail include simple humeral fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The Piccolo Composite Humeral and Proximal Humerus Nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the humerus.

**System Description**

The Piccolo Composite Nailing System includes humeral and proximal humerus nails, interlocking screws and a set of instruments.

The Piccolo Composite Nail is a cylindrical solid rod, made of carbon fiber reinforced polymer. The humeral nail diameter ranges from 7 mm to 8.5 mm, with lengths in the range of 180 mm to 280 mm. The dimensions of the proximal humerus nail are 8 mm diameter (11 mm at proximal end), and length of 150 mm. The nails provide for holes at proximal and distal sections, designed for the insertion of self-tapping, titanium-alloy-made, interlocking screws. The nails have a closed, pointed distal end, and their proximal end incorporates a thread enabling connection of insertion/extraction instrumentation.

**Substantial Equivalence**

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

Biomechanical evaluation demonstrates comparable mechanical properties to the predicate device.

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

JUN 21 2010

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

Re: K100497
Trade/Device Name: Piccolo Composite Nailing System (previously named the Quantum IM Composite Nailing System)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: June 6, 2010
Received: June 15, 2010

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,

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):** K100497

**Device Name:** Piccolo Composite Nailing System

(Previously named the "Quantum IM Composite Nailing System")

**Indications for Use:**

Piccolo Composite Humeral and Proximal Humerus Nails

Indications for the Piccolo Composite Humeral Nail and Proximal Humerus Nail include simple humeral fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathological fractures; reconstruction, following tumor resection and grafting. The Piccolo Composite Humeral and Proximal Humerus Nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the humerus.

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 MXM

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

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