K110322(1/2)

MAR - 4 2011

Section 3: 510(k) Summary

Submitter's Name and Address	Mylad Orthopedic Solutions, LLC 8803 Windy Creek Way McLean, Virginia 22102 Phone: (793)738-6547 Facsimile: (661)885-4447
Contact Person	Scott Edwards, M.D.
Date of Summary:	January 20, 2011
Proprietary Name of Device:	OlecraNail® Intramedullary Fixation System
Common/Usual Name:	Intramedullary nail
Classification Name:	Rod, Fixation, Intramedullary and Accessories per 21 CFR section 888.3020
Legally Marketed Equivalent Devices:	Acumed ulna shortening osteotomy guide Biomet Premier Total Knee Instrumentation Acumed Congruent Bone Plate System (K063460) Mylad OlecraNail® Intramedullary Fixation System (K090091)

Summary of Device:
The OlecraNail® intramedullary nail is a fixation device that has been previously cleared for marketing (K090091). Accessories are being added to the system that will offer optional advantages in terms of how the procedure is accomplished, specifically how the bone is cut, the drill holes are measured, and how the nail is removed.

Intended Use:
The OlecraNail® Intramedullary Fixation System and accessories are intended for the surgical fixation of all fractures and surgical osteotomies of the proximal ulna in the acute or chronic setting.

Technological Characteristics of the Device Compared to the Predicate Devices:
The material, design, and intended use of the accessories for the OlecraNail® Intramedullary Fixation System are identical or similar to at least one of the listed predicates. There are no technological characteristics that raise new issues of safety or effectiveness.

Non-Clinical Tests:
Human cadaveric testing validated the design of accessories for the OlecraNail® Intramedullary Fixation System. Details of these tests are included in this Special 510(k) application.

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

Mylad Orthopedic Solutions, LLC
% Scott Edwards, M.D.
8803 Windy Creek Way
McLean, Virginia 22102

MAR - 4 2011

Re: K110322
Trade/Device Name: OlecraNail® Intramedullary Fixation System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, NDE
Dated: January 24, 2011
Received: February 03, 2011

Dear Dr. Edwards:

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

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Section 2: Statement of Indications for Use

510(k) Number K110322

Device Name: OlecraNail® Intramedullary Fixation System

Indications for Use:

The OlecraNail® Intramedullary Fixation System and accessories are intended for the surgical fixation of all fractures and surgical osteotomies of the proximal ulna in the acute or chronic setting.

Prescription Use X OR Over The Counter Use _____
(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)

for M. Nilsen

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

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