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510(k) Summary of Safety and Effectiveness

TRIMED EASYLOCK OSTEOSYSTEM XXS PLATES

Submitted/Distributed By:	TriMed, Inc. 27533 Avenue Hopkins Santa Clarita, CA 91355 (800)633-7221
Registration No.:	2031009
Manufactured By:	Biotech International 305, Allée de Craponne 13300 Salon De Provence France
Registration No.:	3005270144
Prepared By/Contact Person:	Doug Steinberger Phone: (661)255-7406 Fax: (661)254-8485
Proprietary Name:	Mini Plates or XXS Plates
Classification:	Class II: Screw, Fixation, Bone HWC – Section 888.3040 Class II: Plate, Fixation, Bone HRS – Section 888.3030
Summary Preparation Date:	July 28, 2011

Indications for Use:

The EasyLock XXS Plates are indicated for fixation of fractures in phalangeal and metacarpal bones.

Device Description

The XXS Plates utilize the same integrated locking system for screws as the Xtremities Plates cleared in K050681. The titanium plates have PEEK-Optima® inserts which enables the screws to be locked at the desired angle by means of a "self-tapping" effect. The XXS Plates are thinner and smaller diameter screws (1.7mm) have been designed for use in small bones including the metacarpals and phalanges.

Substantial Equivalence Discussion

When compared to the predicate devices listed below, substantial equivalence is based upon similarities in design features and dimensions, overall indications for use, and material composition.

510(k) Number	Device Name or System	Manufacturer
K050681	EasyLock Osteosystem	Manufactured By: Biotech International Distributed By: TriMed, Inc.
K081546	Small Bone Locking Plating System	DePuy Orthopaedics
K961497	Profyle Hand and Small Fragment System	Stryker, Howmedica

The new product does not change the intended use or scientific principles used for safe and effective implantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

TriMed Inc.
% Doug Steinberger
27533 Avenue Hopkins
Santa Clarita CA 91355

OCT - 6 2011

Re: K111266
Trade/Device Name: EasyLock Osteosystem XXS Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: HRS/HWC
Dated: September 20th, 2011
Received: September 23rd, 2011

Dear Mr. Steinberger:

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): unknown K111266

Device Name: EasyLock Osteosystem XXS Plates

Indications For Use:

The EasyLock XXS Plates are indicated for fixation of fractures in phalangeal and metacarpal bones.

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 K111266