MAY 10 2012 K112794 1/2

510(k) Summary of Safety and Effectiveness

TRIMED EOS SMALL BONE FIXATION SYSTEM

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:	TriMed EOS Small Bone Fixation System
Classification:	Class II: Screw, Fixation, Bone HWC – Section 888.3040 Class II: Plate, Fixation, Bone HRS – Section 888.3030 Class II: Staple, Fixation, Bone JDR – Section 888.3030 Class II: Pin, Fixation, Smooth HTY – Section 888.3040
Summary Preparation Date:	September 9, 2011

I. Indications for Use:

The components of the TriMed EOS Small Bone Fixation System are indicated for use in osteosynthesis, osteotomy, and arthrodesis of the following areas of the body:

Large Cannulated Compression Screws – bones in the foot

Cannulated Compression Screws – small bones in the hand and foot

Snap-Off Screws – small bones in the foot

Bone Plates – first metatarso-phalangeal joint

Staples & Pins – small bones in the hand and foot

II. Device Description

The TriMed EOS Small Bone Fixation System components are designed to provide internal fixation of various bones. The Cannulated Compression Screws are available in 7.3mm, 4.5mm, 3.0mm, and 2.5mm diameters while the Snap-Off Screws are available in a 2.0mm diameter. The 1.30mm thick Bone Plates utilize 2.7mm Bone Screws to secure the plate to the bone, and both items are available in various lengths. All screws and plates are available in implant grade Ti6AL4V Titanium. Staples and Pins are available in diameters ranging from 1.0mm to 2.5mm and are available in implant grade Ti6AL4V Titanium, 316L Stainless Steel, or Nitinol (NiTi).

III. Substantial Equivalence Discussion

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

510(k) Number	**Predicate Device (Manufacturer)**	**TriMed EOS Small Bone Fixation Device**
K093676	Omnitech Large Compression Screws (TriMed)	Large Cannulated Compression Screws
K050681	Omnitech Compression Screws (TriMed)	Cannulated Compression Screws
K991477	SPIN Snap-Off Screws (NewDeal)	Snap-Off Screws
K021626 & K050681	Hallu Plates (NewDeal) EasyLock Osteosystem Plates (TriMed)	Bone Plates
K011716, K070031, & K070033	Uni-Clip Staple (NewDeal), Memory Staple (MemoMetal Technologies), & Varisation Staples (MemoMetal Technologies)	Staples & Pins

An engineering analysis has been conducted to compare the strength of the EOS Small Bone Fixation System components to the predicate devices to provide justification of the safety and effectiveness of the TriMed EOS Small Bone Fixation devices. In addition to the engineering analysis, mechanical tests, functional implant and instrumentation tests, corrosion testing, and biocompatibility tests have been performed to support the substantial equivalence of the EOS Small Bone Fixation System components to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAY 10 2012

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

Re: K112794
Trade/Device Name: EOS Small Bone Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC, JDR, HTY
Dated: April 26, 2012
Received: April 27, 2012

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,

for

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~~ K112794

Device Name: EOS Small Bone Fixation System

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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 K112794