JAN 14 2005

K043263

510(K) Summary of Safety and Effectivenss
TRIMED, INC. ULNAR OSTEOTOMY PLATE

Submitted By:	TriMed, Inc. 25768 Parada Drive Valencia, CA 91355 (800)633-7221
Registration #:	2031009
Prepared By/Contact Person:	Kelli Anderson Phone: (661) 312-7150 Fax: (661) 254-8485
Proprietary Name:	TriMed Ulnar Osteotomy Plate
Classification:	Class II: Bone Fixation Plates Section 888.3030
Classification Code:	HRS
Summary Preparation Date:	November 22, 2004

Intended Use:

The TriMed Unlar Osteotomy Plate is intended for use in osteotomy procedures of the ulna.

Substantial Equivalence:

K952766 Rayhack Osteotomy System
K030310 Synthes 3.5/4.5 mm. LCP Metaphyseal Plates

Kelli Anderson
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

TriMed, Inc.
C/o Kelli Anderson
Regulatory Affairs Specialist
25768 Parada Drive
Valencia, California 91355

Re: K043263
Trade Name: TriMed Ulnar Osteotomy Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: November 22, 2004
Received: November 24, 2004

Dear Ms. Anderson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043263

Device Name: TriMed Ulnar Osteotomy Plate

Indications For Use: The TriMed Ulnar Osteotomy Plate is intended for use in osteotomy procedures of the ulna.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for _____
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 043263