MAY 22 2003

BIOMET K031334
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Summary of Safety and Effectiveness

Applicant or Sponsor:

Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0578

Contact Person:

Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0578
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name: Texas T - Plate

Common or Usual Name: Stainless Steel Bone Plates and Buttress Pins.

Classification Name:

Plate, Fixation, Bone (21CFR 888.3030)
Buttress Pin, Fixation, Bone (21CFR 888.3040)
Screw, Fixation, Bone (21 CFR 888.3040)

Legally Marketed Device(s) to which Substantial Equivalence is Claimed (Predicate Devices): The Texas T – Plate System is Substantially Equivalent to the Synthes Dorsal Distal Radius Plating System (K 962616), and its components are Substantially Equivalent to those marketed by Industrias Quirurgicas de Levante S.L. (K 020221).

Device Description: The Texas T – Plate is an Anatomical Plating System for fractures of the distal radius. All components will be manufactured of 316 LVM Stainless Steel in accordance with ASTM F – 138 standards.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

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Indications for Use: The Texas T – Plate Distal Radius Plating System is indicated for use in open reduction and internal fixation of fresh fractures, osteotomies, Arthrodesis, and revision procedures of the distal radius.

Summary of Technology: This device utilizes standard technology that is commonly known by Orthopedic Surgeons. The technology utilized conforms to commonly accepted standards of practice for internal fixation of metallic bone plates.

Non-Clinical Testing: The Texas T – Plate device was subjected to a Non-Clinical cantilever bending test wherein it was found to be able to sustain a higher load than either the IQL Small Epiphysis Plate or the IQL T – Plate that were identified as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2003

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corporation
P.O. Box 587
Warsaw, IN 46581-0587

Re: K031334
Trade/Device Name: Texas T - Plate
Regulation Number: 21 CFR 888.3030, 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HRS, HWC
Dated: April 25, 2003
Received: April 28, 2003

Dear Mr. Baker:

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 (301) 594-4659. 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/dsma/dsmamain.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

510(k) Number (IF KNOWN): K031334

Device Name: Texas T - Plate

Indications for Use:

The Texas T – Plate Distal Radius Plating System is indicated for use in open reduction and internal fixation of fresh fractures, osteotomies, arthrodesis, and revision procedures of the distal radius.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K031334