



CORPORATE HEADQUARTERS

APR 14 1998

K980370

Summary of Safety and Effectiveness

Proprietary Name: BioSymMetRiC™ Proximal Interphalangeal Joint Fixator

Classification Name and Product Code: Similar devices are classified in many different categories. The following classifications have been used for similar products:

- 1) Smooth or threaded metallic bone fixation fastener (888.3040), 87JDW or 87HTY
- 2) Appliance, fixation nail/blade/plate combination, multiple component (888.3030), 87KTT

Device Classification: Class II

Intended Use:

- 1) Complex fracture-dislocations of the proximal Interphalangeal joint.
- 2) Unstable PIP dislocations
- 3) Post-traumatic contracture of the PIP joint

Device Description: The BioSymMetRiC Proximal Interphalangeal Joint Fixator is an external fixator to assist in the healing of fractures or other bone cutting procedures of the fingers. The device is an external frame to provide stability and distraction for pins inserted through the skin into the bone.

Potential Risks: The potential risks associated with this device include but are not limited to:

Infection	Blood vessel damage	Bone Fracture
Hematoma	Deformity of the joint	Soft tissue imbalance
Pin loosening	Fracture of device	Excessive Wear
Nerve Damage	Metal sensitivity	Disassociation of the components

Substantial Equivalent Device: Compass® Proximal Interphalangeal (PIP) Hinge from Smith & Nephew Richards cleared through 510(k) K970713.

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

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
•Director, Regulatory Affairs
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

APR 14 1998

Re: K980370
BioSymMetric™ Proximal Interphalangeal Joint Fixator
Regulatory Class: II
Product Code: KTT
Dated: January 27, 1998
Received: January 30, 1998

Dear Ms. Beres:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

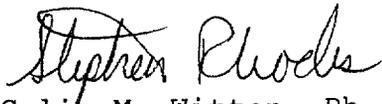
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Patricia Sandborn Beres

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for 

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

Enclosure

510(k) Number (if known): _____

Device Name: BioSymMetRic™ Proximal Interphalangeal Joint Fixator

Indications For Use:

- 1) Complex fracture-dislocations of the proximal Interphalangeal joint.
- 2) Unstable PIP dislocations
- 3) Post-traumatic contracture of the PIP joint

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)

Division of **General Restorative Devices**

510(k) Number _____

K980370