OCT 13 1998

SUMMARY OF SAFETY AND EFFECTIVINESS

K982982

SPONSOR: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

CONTACT PERSON: Julie Ryan

PROPRIETARY NAME: Mini –Fixator for Colles Fractures

Common or Usual Name: External Bones Fixator

Device Code:

Device Classification: Class II

Device Name: Mini-Fixator for Colles Fractures

INTENDED USE: The Mini-Fixator for Colles Fractures are indicated for use with a Colles fractures requiring external fixator. The half pins are surgically implanted the remainder of the device is external.

DEVICE DESCRIPTION: There are several pieces that are included in this device package. This also includes the instrument required. The pieces are the mini hammer, the distractor bar, half pins, drill bit, drill guide, clamp assembly, 3/32 x 5 drill bit, tommy bar, alignment guide, 2.5 mm screwdriver and silicone pin caps. These are packaged in a single container for single use and are sterile.

POTENTIAL RISK: The potential risk is the same for any surgery, which include the following but are not limited to:
Non-union or delayed union
Bending or fracture of implant
Metal sensitivity or allergic reaction to foreign body
Bone resorption
Decrease in bone density due to stress shielding
Pain, discomfort or abnormal sensation due to the presence of the device
Nerve damage due to surgical trauma
Necrosis of the bone

SUBSTANTIAL EQUIVALENCE: There are several other devices similar to the sponsor already on the market. They are manufactured by ACE DePuy, Trend Medical, Zimmer, OrhtoFrame and SE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 1998

Ms. Julie K. Ryan
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K982982
Trade Name: Mini-Fixator for Colles Fractures
Regulatory Class: II
Product Code: HRS
Dated: August 24, 1998
Received: August 26, 1998

Dear Ms. Ryan:

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 (Premarket 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.

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: K982982
DEVICE NAME: Mini-Fixator for Colles Fractures

INDICATIONS FOR USE:

The Mini-Fixator for Colles Fractures is intended for use in the repair of Colles fractures. The device is intended for single use only and is external with internal pins.

(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 K982982