K984209

FEB 3 1999

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet Inc.
Airport Industrial Park
Warsaw, Indiana 46580

Proprietary Names: Stainless Steel Taper Foreman Nail Cannulated Screw
Stainless Steel Cannulated Screw, Short Thread
Stainless Steel Pediatric Cannulated Cancellous Screw
Stainless Steel Cannulated Hip Screw
Stainless Steel Cannulated Screw

Titanium Cannulated Cancellous Screw
Titanium Cannulated Cancellous Screw, Long Screw
Titanium Cannulated Cancellous Screw, Fully Threaded
Titanium Alloy Cannulated Screw

Common or Usual Name: Cannulated Screw

Classification Name: smooth or threaded metallic bone fixation fastener (21 C.F.R. §888.3040)

Device Classification: Class II

Device Product Code: 87 HWC-screw, fixation, bone

Intended Use: The cannulated screws may be used for fixation of long bone fractures and for bone reconstruction (i.e. fresh fractures, osteotomy, revision procedure where other treatments or devices have failed, arthrodesis, and in conjunction with other fixation hardware). These cannulated screws are not to be used for spinal application or Carpal Tunnel Sydrome.

Device Description: Various styles of stainless steel and titanium alloy cannulated screws. Screw diameters range from 3.5mm to 8.0mm and 6.5mm to 8.0mm, respectively.

Potential Risks: The risks associated with these devices are the same as with any metallic internal fixation device. These include but are not limited to the following:

-Delayed or nonunion which may lead to breakage of the implant
-Bending or fracture of the implant
-Loosening or migration of the implant
-Metal sensitivity, or allergic reaction to a foreign body
-Limb shortening or decrease in bone density due to compression of the fracture or bone resorption
-Pain, discomfort, or abnormal sensations due to the presence of the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 1999

Ms. Dalene Hufziger Binkley
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K984209
Trade Name: Cannulated Screws
Regulatory Class: II
Product Code: HWC
Dated: November 20, 1998
Received: November 24, 1998

Dear Ms. Binkley:

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,

Neil R.P. Ogden 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): 984209

DEVICE NAME: Cannulated Screws

INDICATIONS FOR USE:

The cannulated screws maybe used for fixation of long bone fractures and for bone reconstruction (i.e. fresh fractures, osteotomy, revision procedures where other treatments or devices have failed, arthrodesis, and in conjunction with other fixation hardware.) These cannulated screws are not to be used for spinal application or Carpal Tunnel Syndrome.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984209

(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)