K011451

DEC 1 0 2001

SUMMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581 –0587

Contact Person: Sara Bailey Shultz
Regulatory Specialist

Proprietary Name: ReUnite™ Fusion Screw

Common or Usual Name: Arthrodesis screw

Classification Name: Screw, Fixation, Bone, Non-spinal, Non-metallic (888.3040)
Pin, Fixation, Smooth, Non-metallic (888.3040)

Device Product Code: 87HWC and HTY

Substantially Equivalent Devices: LactoSorb® Bone Pin (K953194 and K990291), ReUnite™ Screw (K992301), OrthoSorb® Absorbable Pin (K901456), Kirschner Orthopedic Wire (K850631)

Indications for Use: The ReUnite™ Fusion Screw is indicated for proximal interphalangeal (PIP) joint arthrodesis and distal interphalangeal (DIP) joint arthrodesis in the presence of appropriate protection or immobilization.

Device Description: The ReUnite™ Fusion Screw is made out of LactoSorb® and has an elongated, tapered head at the proximal end, a smooth shaft in the middle, and a threaded portion at the distal end. A three-pronged driver is used to insert the three-slotted screw head. During insertion, as the threads gain purchase in the distal bone fragment, the tapered head is completely countersunk within the bone. After insertion, the driving head breaks off.

Basis of Substantial Equivalence: The ReUnite™ Fusion Screw has the same intended use and material, and similar design when compared to the following bone fixation devices:

1. LactoSorb® Bone Pin, Biomet Inc., K953194 and K990291
2. ReUnite™ Screw, Biomet Inc., K992301
3. Kirschner Orthopedic Wire, Kirschner Medical Corporation, K850631

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2001

Ms. Sara Bailey Shultz
Regulatory Specialist
Biomet
P.O. Box 587
Warsaw, Indiana 46581

Re: K011451
Trade/Device Name: ReUnite™ Fusion Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 26, 2001
Received: September 28, 2001

Dear Ms. Shultz:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walker, MD

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): K011451

DEVICE NAME: ReUnite™ Fusion Screw

INDICATIONS FOR USE:

The ReUnite™ Fusion Screw is indicated for proximal interphalangeal (PIP) joint arthrodesis and distal interphalangeal (DIP) joint arthrodesis in the presence of appropriate protection or immobilization.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use No
(Optional Format 1-2-96)

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

510(k) Number K011451