DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 1996

Mr. Jeffry B. Skiba
Vice President of Engineering
Orthopaedic Biosystems Limited, Inc.
7320 East Butherus, Suite 206
Scottsdale, Arizona 85260

Re: K963433
Threaded Fixation Pin
Regulatory Class: II
Product Code: JDW
Dated: August 28, 1996
Received: August 30, 1996

Dear Mr. Skiba:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 "dsmo@fdadr.cdrh.fda.gov".

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

Device Name: Threaded Fixation Pin

Indications For Use: The device is intended for the bones of the foot and hand.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963433

FDA
1-800-638-2041

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center(HFZ 401)
Attn: 510K
9200 Corporate Blvd.
Rockville, MD 20850

1-301-443-8129 510K office

1-301-594-2977 Fax

www.fda.gov/cdrh

April 29, 1996

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Attn: Document Mail Clerk

Reference: 510(k) Notification - Small Fragment Bone Screw

This submission is to notify you of the intention of Orthopaedic Biosystems, Ltd., to manufacture and market the following device: Small Fragment Bone Screws

•Administrative Information:

The proposed device will be sponsored by Orthopaedic Biosystems Ltd., 7320 E. Butherus, Ste 206, Scottsdale, Arizona, 85260.

Establishment Regulation Number: 2028229

All correspondence should be directed to

Jeffry B. Skiba,
Vice-President, Engineering and Manufacturing,
Orthopaedic Biosystems,
7320 E. Butherus, Ste 206,
Scottsdale, Arizona, 85260.

•Device Identification:

Proprietary Name: Compression Screw

Common Name: Bone Screw, 1.5 , 1.8, 2.0 mm thread major diameters.

Classification Name and Reference: 21 CFR 888.3040

Proposed Regulatory Class: Class 2

•Device Descriptive Information:
The small fragment bone screw is a screw designed for use in the small bones of the hand and foot.

Intended Use:
The device is intended for the bones of the extremities such as the small bones of the foot and hand and are not indicated for the pedicles of the spine.

Device Description:
The devices are partially threaded, stainless steel or titanium screws. The head is larger than the shank to compress the surface opposing the thread form. The head is cut with a cruciform pattern for attachment to a driving screwdriver. A drawing is attached in Appendix A.

7320 E. Butherus • Suite 206 • Scottsdale • Arizona • 85260
(602) 596-4066 • (800) 487-9128 • FAX (602) 596-2180

Orthopaedic Biosystems Ltd., Inc.

Materials:
Stainless Steel 316 LVM/LS conforming to ASTM F-138 or Titanium conforming to ASTM F-67. Attached in Appendix B.
Titanium to be supplied by Titanium Industries or Dynamet. Stainless Steel to be provided by Carpenter Steels.

Manufacturing Facility:
LaVezzi Precision, 999 Regency Drive, Glendale Heights, Illinois, 60139-2281.

Labeling:
See attached label sample in Appendix C

Contraindications:
Pedicle screw fixation.
Osteoporotic Bone

Sterility Information:
The devices may be provided non-sterile and it will be recommended that sterilization be performed in accordance to the AAMI Standards and recommended practices for autoclave sterilization. Cycle: pre-vacuum, temperature 270 degrees F, Exposure time 20 minutes, SAL 10-6, sterility validation method - biological indicator.

The devices may be provided sterile in properly validated double pouched mylar/tyvek bags. Sterility will be achieved by exposure to gamma radiation of a minimum of 2.5 Mrads to assure an SAL of 10^6. Sterilization to be validated per AAMI Method 1, 2, or 3 or U.S.P. 23.

ackaging Information:
Devices will be packaged in a clean, plastic tube, suitable mylar/tyvek pouches with identification labels.

Substantial Equivalence Information:
Synthes - Mini-fragment screws - see attached Appendix D

Thank you.

7320 E. Butherus • Suite 206 • Scottsdale • Arizona • 85260
(602) 596-4066 • (800) 487-9128 • FAX (602) 596-2180