

SEP 25 1997

K973204

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15/16

Osteo BOS™ System in Stainless Steel

510(k) Premarket Notification

**510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
OSTEO BOS™ SYSTEM IN STAINLESS STEEL**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677
201-825-4900

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date Summary Prepared:

September 19, 1997

Device Identification

Proprietary Name:

Osteo BOS™ System in Stainless Steel

Common Name:

Stainless Steel Plating System

Classification Name and Reference:

Plate, Fixation, Bone
21 CFR §888.3030

Predicate Device Identification

The subject Osteo BOS™ System in Stainless Steel components are substantially equivalent to similar bone plates offered by Synthes.

Device Description

The Osteo BOS™ System in Stainless Steel components are used for fracture fixation of long and small bones. All Osteo BOS™ System components are manufactured from ASTM F-138-92 Stainless Steel and include the following:

- Plate - Wide (ø6.5mm/ø4.5mm)
- Plate - Narrow (ø6.5mm/ø4.5mm)
- Plate - Wide (ø4.0mm/ø3.5mm)
- One-Third Tubular Plate (ø4.0mm/ø3.5mm)
- Plate (ø2.7mm)

*K973204 page 2 of 2**16/16*Osteo BOS™ System in Stainless Steel510(k) Premarket Notification**Intended Use**

The Osteo BOS™ System in Stainless Steel components are intended for fracture fixation of long and small bones.

Statement of Technological Comparison

The subject Osteo BOS™ System in Stainless Steel components are substantially equivalent in design and intended use to the predicate bone plates offered by Synthes. Both the subject and predicate plates are manufactured from stainless steel.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics
59 Route 17
Allendale, New Jersey 07401-1677

SEP 25 1997

Re: K973204
Osteo BOS™ System in Stainless Steel
Regulatory Class: II
Product Code: HRS
Dated: August 25, 1997
Received: August 26, 1997

Dear Ms. Sutton:

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.

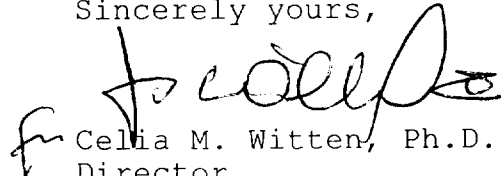
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Kate Sutton

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,


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

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510(k) Number (if known): K973204Device Name: Osteo BOS™ System in Stainless Steel

Indications For Use:

The indications for use of the Osteo BOS™ System in Stainless Steel bone plates, in keeping with those of other legally marketed bone plates and bone screws, are as follows.

- The Osteo BOS™ System in Stainless Steel components are intended for long and small bone fracture fixation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restorative Devices

K973204Prescription Use X

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)