# 510(k) PREMARKET NOTIFICATION
# SUMMARY OF SAFETY AND EFFECTIVENESS
# OSTEO BOS™ SYSTEM PRODUCT LINE EXTENSION

DEC - 9 1997

## 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 9, 1997

## Device Identification

**Proprietary Name:**

Osteo BOS™ System Product Line Extension

**Common Name:**

Plating/Fixation System

**Classification Name and Reference:**

Plate, Fixation, Bone
21 CFR §888.3030
Smooth or Threaded Metallic Bone
Fixation Fasteners
21 CFR §888.3040

## Predicate Device Identification

The subject Osteo BOS™ System product line extension components are substantially equivalent to similar bone plates and Kirschner wires offered by Synthes.

## Device Description

The Osteo BOS™ System product line extension components are used for fracture fixation on various small and long bones. All Osteo BOS™ System product line extension components are manufactured from Titanium alloy and include the following:

- Oblique T-Plate, ø4.0/ø3.5
- One-Third Tubular Plate, ø4.0/ø3.5
- Kirschner wire with trocar point

## Intended Use

The Osteo BOS™ System product line extension bone plates are intended for internal fracture fixation of various long and small bones. The Kirschner wires are intended for use in skeletal traction for alignment and reduction of long bone fractures, as guide wires in hip pinning, and as fracture fixation devices in certain other small bone fractures.

## Statement of Technological Comparison

The subject Osteo BOS™ System product line extension components are substantially equivalent in design and intended use to the predicate bone plates and Kirschner wires offered by Synthes. The subject plates are manufactured from Titanium alloy, and the predicate plates are manufactured from CP Titanium. Both subject and predicate Kirschner wires are manufactured from Titanium alloy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1997

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

Re: K973438
Trade Name: Osteo BOS System Product Line Extension
Regulatory Class: II
Product Codes: HRS and HTY
Dated: September 9, 1997
Received: September 10, 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.

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): K973438

Device Name: Osteo BOS™ System Product Line Extension

Indications For Use:

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

The indications for each of the Osteo BOS™ System product line extension bone plates are:

- Internal fracture fixation of long and small bones.

The indications for the Kirschner wires with a trocar point are:

- For use as guide wires in hip pinning procedures.
- For use in aligning and reducing long bone fractures.
- For use in securing non-long bone fractures such as olecranon fractures, patella fractures, tibial plateau fractures, small hand and foot bone fractures, humeral, and humeral, radial and ulnar fractures, etc.
- For use with cerclage wire/cable in treating greater trochanter fractures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973438