

JUN 22 1998

K98 1309

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for the  
Osteo I-C Humeral Nail System**

**Submission Information:**

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

Osteonics Corporation  
59 Route 17  
Allendale NJ 07401-1677

**Contact Person:**

Marybeth Naughton  
Regulatory Affairs Team Member

**Date of Summary Preparation:**

April 6, 1998

**Device Identification**

**Proprietary Name:**

Osteo I-C Humeral Nail System  
Includes the following components:

- Osteo I-C Humeral Nail
- Osteo I-C Humeral Nail Locking Screw
- Osteo I-C Humeral Nail Compression Screw
- Osteo I-C Nail Humerus Protection Screw

**Common Name:**

Interlocking-Compression Humeral Nail System

**Classification Name/Reference:**

Intramedullary Fixation Rod  
21 CFR §888.3020

**Predicate Device Identification:**

The components of the Osteo I-C Humeral Nail System are substantially equivalent to those of the Biomet Uniflex™ Humeral Nail System and the Synthes Titanium Solid Nail System.

**Description of Devices:**

The Osteo I-C Humeral Nail System consist of the Osteo I-C Humeral Nail, a cylindrical tube which is intended to aid in the alignment and stabilization of humeral fractures and associated components include the Osteo I-C Humeral Nail Locking Screw, the Osteo I-C Humeral Nail Compression Screw and the Osteo I-C Nail Humerus Protection Screw which are intended to secure the Osteo I-C Humeral Nail in place.

**Intended Use:**

The Osteo I-C Humeral Nail System is indicated for single-use in the humeral shaft to address the following indications: fractures of the humeral shaft, non-unions, malalignments, pathologic fractures, and impending pathologic fractures.

**Statement of Technological Comparison:**

The design, materials, and intended use of the Osteo I-C Humeral Nail System are substantially equivalent to those of predicate Biomet Uniflex™ Humeral Nail System and the Synthes Titanium Solid Humeral Nail.

**Performance Data:**

The comparison of the Osteo I-C Humeral Nail System to predicate systems which have been determined to be substantially equivalent through 510(k) premarket notifications demonstrates that no additional performance data are necessary.



JUN 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Elizabeth A. Staub  
Director, Quality Assurance  
and Regulatory Affairs  
Osteonics Corporation  
59 Route 17  
Allendale, New Jersey 07401-1677

Re: K981309  
Osteo I-C Humeral Nail System  
Regulatory Class: II  
Product Code: HSB  
Dated: April 9, 1998  
Received: April 10, 1998

Dear Ms. Staub:

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.

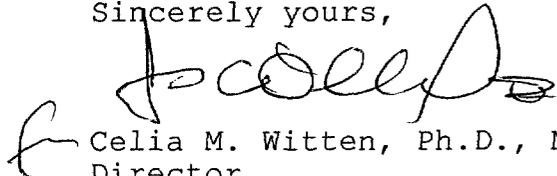
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

510(k) Number (if Known): K 981309

Device Name: Osteo I-C Humeral Nail System

Indications For Use:

The use of the Osteo I-C humeral Nail System is intended to aid in the alignment and stabilization of humeral fractures. The use of this system is indicated for diagonal and short oblique fractures of the humeral diaphysis as well as fractures of the metaphyseal and some comminuted humeral fractures. The Osteo I-C Humeral Nail System is intended for single use only.

**Indications:**

- ▶ Fractures of the humeral shaft
- ▶ Non-unions
- ▶ Malalignments
- ▶ Pathologic humeral fractures
- ▶ Impending pathologic humeral fractures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K981309

Prescription Use X  
(per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)