

FEB 20 2004

**510(K) SUMMARY**

**Subject 510(k) Number**

K040199  
page 1 of 1

**Sponsor**

Osseus, LLC

3131 Princeton Pike  
Bldg 5, Suite 200  
Lawrenceville, NJ 08648

**Official Contact**

Shawn T. Huxel, President/GM  
3131 Princeton Pike  
Bldg 5, Suite 200  
Lawrenceville, NJ 08648  
Phone - (908) 997-0127  
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**Proprietary Name**

Osse-Lign

**Common Name**

Metallic Internal Fixation Device

**Classification Name and Reference**

888.3010 - Bone Fixation Cerclage

**Regulatory Class**

Class II

**Device Product Code**

(Panel 87) JDQ

**Date Prepared**

27 January, 2004



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 20 2004

Mr. Shawn T. Huxel  
President/General Manager  
Osseus, LLC  
3131 Princeton Pike  
Building 5, Suite 200  
Lawrenceville, New Jersey 08648

Re: K040199

Trade/Device Name: 1.5 mm Osse-Lign Internal Fracture Fixation System  
Regulation Number: 21 CFR 888.3010  
Regulation Name: Bone fixation cerclage  
Regulatory Class: II  
Product Code: JDQ  
Dated: January 27, 2004  
Received: January 29, 2004

Dear Mr. Huxel:

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.

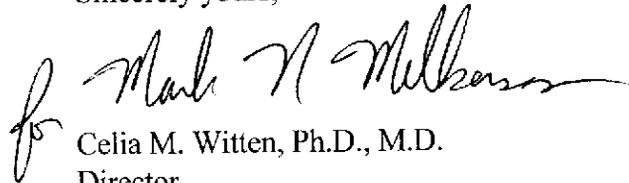
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Shawn T. Huxel

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510 (K) NUMBER IF KNOWN: K040199

DEVICE NAME: 1.5 mm Osse-Lign Internal Fracture Fixation System

The Osse-Lign System is indicated for general orthopedic repairs. This includes such procedures as long bone fractures, bone grafting and reinforcement of bone. This system may also be used for supplementary fixation and reduction with approved bone plates, screws, pins, nails and bone grafting material.

#### Long Bone Fractures

- Femur fractures
- Tibia fractures
- Humerus fractures

#### Joint Fractures

- Ankle fractures
- Knee Fractures
- Hip Fractures
- Shoulder Fractures
- Elbow Fractures

#### Other bone fractures

- Olecranon
- Pelvis fractures
- Patella fractures
- Acetabular fractures
- Trochanteric reattachment
- Fixation of fractures in conjunction with I/M nailing and plating techniques
- Stabilization of cortical onlay strut graft
- Temporary reduction techniques for ORIF (Open Reduction Internal Fixation)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

or

Over-the-Counter Use \_\_\_\_\_  
(Optional Format 1-2,1996)

*for* Mark N. Millers  
 (Division Sign Off)  
 Division of General, Restorative,  
 and Neurological Services