K971962

510(k) SUMMARY
Osteo Kirschner Wires

AUG 11 1997

Submission Information

Name and Address of the Sponsor:
Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Name and Address of the Manufacturer:
Osteo AG
Bohnackerweg 1
CH-2545 Selzach, Switzerland

Contact Person:
Terry Sheridan
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale NJ 07401

Date of Summary Preparation:
May 27, 1997

Device Identification

Proprietary Name:
Osteo Kirschner Wires

Common Name:
Kirschner wires (K wires)

Classification Name and Reference:
Smooth or Threaded Metallic Bone Fixation Fasteners
21 CFR §888.3040

Predicate Device Identification

The Osteo Kirschner Wires are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteo Kirschner Wires (Osteo AG)
- Kirschner Wires (Smith + Nephew Richards)
- Kirschner Wires (Synthes)

Device Description

The subject Kirschner Wires include both threaded and smooth components, and are available in a range of diameters and lengths. Both the threaded and smooth designs feature a trocar point. This submission includes both sterile and non-sterile product offerings.

Intended Use

Kirschner Wires are intended for use in skeletal traction for alignment and reduction of long bone fractures, and as guide wires in hip pinning, and as fracture fixation devices in certain other small-bone fractures.

Indications and Contraindications

Indications

- 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, radial and ulnar fractures; etc.
- For use with cerclage wire/cable in treating greater trochanter fractures.

Statement of Technological Comparison:

The subject and predicate devices share the same intended uses. The subject and predicate devices are both manufactured from implantable stainless steel that complies with ASTM F-138-92. The subject Osteo Kirschner Wires come in threaded and smooth designs, as do the predicate devices cited. The subject devices come in diameters and lengths consistent with the range available for the predicate devices.

Performance Data:

As the subject Osteo Kirschner Wires are stainless steel wires with diameters not smaller than those featured in the predicate device systems, testing is not needed to demonstrate that the subject devices are substantially equivalent to other legally marketed Kirschner Wires.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG 11 1997

Re: K971962
Osteo Kirschner Wires
Regulatory Class: II
Product Code: HTY
Dated: May 27, 1997
Received: May 28, 1997

Dear Ms. Sheridan:

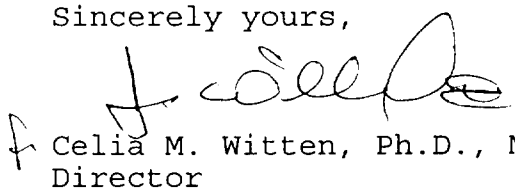
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K_____

Device Name: Osteo Kirschner Wires

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(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____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971962