NOV 19 1999

K993603

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
Wichita™ Fusion Nail Fully Threaded Self-Tapping Screw

Proprietary Name:	Wichita™ Fusion Nail Fully Threaded Self-Tapping Screw
Common Name:	Intramedullary Fixation Rod
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020
Proposed Regulatory Class:	Class II
Device Product Code:	OR (87) HSB
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 359 Veterans Boulevard Rutherford, NJ 07070-2584 (201) 507-7283 Fax: (201) 507-6870

This Special 510(k) submission is intended to address a design modification to the predicate Wichita™ screw. The predicate device is a partially threaded screw manufactured from wrought Vitallium® (CoCr) Alloy which conforms to ASTM standard F1537. This device was found substantially equivalent via the 510(k) process. The subject device is being modified from a partially threaded screw with course thread design to a fully threaded screw with fine thread design. The screw head length is being reduced by 1mm, and the head profile is changing from the square to the rounded design. Additionally, a 25mm screw will be added to the current product line. The intended use of the Wichita™ Fully Threaded Self-Tapping Screw is identical to the Wichita™ Partially Threaded Self-Tapping Screw.

This device is intended for use with the Wichita™ Fusion Nail in cases for intramedullary knee arthrodesis. Arthrodesis is performed to relieve pain and to stabilize a knee joint that has been severely damaged as a result of trauma, infection, or

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failed previous surgeries (including previous total joint replacement). More specific indications include treatment of the sequelae of septic arthritis in patients who are not candidates for total knee arthroplasty, irretrievably failed total knee arthroplasty (either septic or aseptic), Charot arthropathy, painful degenerative knee in patients who are not candidates for total knee arthroplasty, arthrodesis of the knee for salvage in tumor surgery, delayed or non-union after previous arthrodesis of the knee, and any other condition where arthrodesis is the treatment of choice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Ms. Elizabeth A. Staub
Vice President
Regulatory Affairs, Quality Assurance and Clinical Research
Stryker Howmedica Osteonics
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K993603
Trade Name: Wichita™ Fusion Nail Fully Threaded Self-Tapping Screw
Regulatory Class: II
Product Code: HSB
Dated: October 4, 1999
Received: October 25, 1999

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 (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,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993603

Device Name: Wichita™ Fusion Nail Fully Threaded Self-Tapping Screw

Indications for Use:

This device is intended for use with the Wichita™ Fusion Nail in cases for intramedullary knee arthrodesis. Arthrodesis is performed to relieve pain and to stabilize a knee joint that has been severely damaged as a result of trauma, infection, or failed previous surgeries (including previous total joint replacement). More specific indications include treatment of the sequelae of septic arthritis in patients who are not candidates for total knee arthroplasty, irretrievably failed total knee arthroplasty (either septic or aseptic), Charot arthropathy, painful degenerative knee in patients who are not candidates for total knee arthroplasty, arthrodesis of the knee for salvage in tumor surgery, delayed or non-union after previous arthrodesis of the knee, and any other condition where arthrodesis is the treatment of choice.

(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 K993603