

JUN 29 1999

SURGICAL
IMPLANTS
INC.

K991405

962 South Tamiami Trail, Ste. 203, Sarasota, Florida 34326 • Office (941) 366-1882 • Fax (941) 366-1734

June 18, 1999

The Director,
US Food & Drug Administration,
Center for Devices & Radiological Health,
Document Mail Center, HFZ-401,
9200 Corporate Blvd.
Rockville, Maryland, 20850

Attention Dr. Mishra, Orthopedic Device Evaluation Branch.

Re: 510(K 991405) Pre-Market Application for a Line Extension to
Surgical Implants Inc. Omni-Fix, Intra-Medallary Nail System.

Dear Sir,

In reply to your enquirey of June 18, 1999 I present the following statements for
your review on the Omni Fix Humeral nail 510(K) application.

SUMMARY OF SAFETY AND EFFECTIVENESS

PRODUCT RATIONALE & DESCRIPTION

The Omni-Fix, intra-medallary nails were designed to be used for fracture stabilization and
fixation of the femur and tibia. Nails are manufactured from Titanium Alloy (Ti-6Al-4V)
wrought bar stock material as per ISO 5832 part 3 and ASTM F136-84.

SUBSTANTIALLY EQUIVALENT PRODUCTS

We believe that the Omni-Fix, humeral intra-medallary nail system functions in the same
manner and is substantially equivalent to the Biomet, Uniflex nail system which is available
for commercial distribution. The implant material, design rationale, and surgical technique
are substantially the same between the two systems.

MECHANICAL TESTING TO SHOW SAFETY

The mechanical testing of our nails were performed at the University of Teeside (England)
Engineering Materials Test Center following our test Protocol. Tests were carried out on
the departments testing equipment as per ASTM F383-89. Two different mechanical tests
were performed using the smallest size nails. No failures were seen using the test protocol
on the Omni-Fix nails.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Douglas W. Stuart
President
Surgical Implants Inc.
962 South Tamiami Trail
Ste. 203
Sarasota, Florida 34326

Re: K991405
Trade Name: Omni-Fix, Intra-medullary Nail
Regulatory Class: II
Product Code: KTW
Dated: April 14, 1999
Received: April 22, 1999

Dear Mr. Stuart:

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.

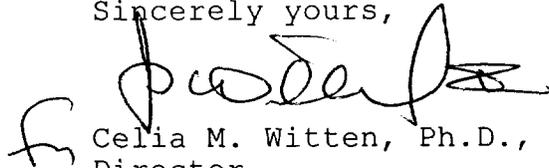
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (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.

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a large, stylized initial "C" on the left side.

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

EXHIBIT 7

STATEMENT OF INDICATION

510(K) Number: K991405
Device Name: Omni-Fix nailing system

Indications For Use:

Statement of Indication

Cases of fracture of the long arm bones are not uncommon and are usually caused by trauma. The surgical re-construction of the humeral is necessary to restore the patients natural alignment of the arm. The intra-medullary nail is used as a scaffold to hold the separate fractured bone sections together, until natural healing of the fracture occurs. The nail creates a sound foundation when the fracture is healed for full load bearing.

Signed: DW Stewart

(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

[Signature] (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991405