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FHIndustrie

K042332

OCT 7 - 2004

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS
TITANIUM TELEGRAPH® HUMERAL NAIL

SPONSOR IDENTIFICATION: Fournitures Hospitalières Industrie
6 Rue Nobel, Z.I. de Kernevez
29000 QUIMPER - FRANCE
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ESTABLISHMENT REGISTRATION NUMBER: 3003898228

OFFICIAL CONTACT PERSON: Christine QUENDEZ
Regulatory Affairs Manager
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DATE PREPARED: AUGUST 23th, 2004

DEVICE TRADE NAME: TITANIUM TELEGRAPH® HUMERAL NAIL

COMMON NAME: Intramedullary rod

REGULATORY CLASS: Class II

DEVICE PRODUCT CODE: 87 HSB

PANEL CODE: 21 CFR 888.3020

DEVICE DESCRIPTION:
The titanium Telegraph® humeral nails are made of titanium and are available in two models :

- a short humeral nail (150mm length)
- a long humeral nail (from 210 to 310mm).

These two models are available in four diameters: 7, 8, 9 and 10mm.
These titanium humeral nails are intended to be used with titanium cancellous screws, available in 15 lengths (from 24 to 50mm) and with a 4mm diameter. The titanium Telegraph® humeral nail and the screws are supplied sterile.

INDICATIONS FOR USE:
The titanium Telegraph® humeral nail is indicated for fractures of the upper extremity and/or the diaphysis of the humerus.

PREDICATE DEVICES:
The titanium Telegraph® humeral nail is similar to the Telegraph® humeral nail previously cleared in K033510.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:
The proposed titanium Telegraph nails have the same intended use and indications for use as the predicate device. Design and manufacturing process is the same.
The only difference is the modification of the material. The proposed devices are made of titanium alloy according to ISO 5832/3 and ASTM F-136 standards. Performance tests were performed. Our proposed devices and the predicate devices were found to have results in compliance with the selected standard.

The following comparative table is provided to further demonstrate equivalence:

	Titanium Telegraph® Humeral nail	**Telegraph® Humeral nail**
Manufacturer	F.H.I	F.H.I
510 K number	Pending	K033510
Intended use	Intended for fractures of the upper extremity and/or the diaphysis of the humerus.	Intended for use for proximal and/or diaphyseal fractures of the humerus.
Material	Titanium alloy	Stainless steel
Cylindrical	Yes	Yes
Sizes Diameter Length	 ∅ 7, 8, 9 and 10 mm Short nail: 150 mm Long nail: 210, 230, 250, 270, 290, 310 mm	 ∅ 7, 8 and 9 mm Short nail: 150 mm Long nail: 210, 230, 250, 270, 290, 310 mm
Interlocking screws	Proximal: 3 self-stable screws Distal: 2 screws in the frontal plane	Proximal: 3 self-stable screws Distal: 2 screws in the frontal plane
Performance tests	Flexion tests on 6 Titanium nail ∅7 and 310mm length, Torsion tests on 6 Titanium nail ∅7 and 310mm length. (according to ASTM F 1264-00)	Flexion tests on 6 Titanium nail ∅7 and 310mm length, Torsion tests on 6 Titanium nail ∅7 and 310mm length. (according to ASTM F 1264-00)
Sterile	Yes (Gamma)	Yes (Gamma)

PERFORMANCES:
Performance testing was performed in accordance with the recommendations set up in the FDA guidance document "Reviewers Guidance Checklist for Intramedullary Rods". The following tests were performed to validate the mechanical characteristics of the Titanium Telegraph humeral nail (according to ASTM F 1264-00 standard):

- Flexion test on 6 titanium Telegraph humeral nail
- Torsion test on 6 titanium Telegraph humeral nail

All results demonstrate that the proposed device is in accordance with the mechanical resistances required by the ASTM F 1264-00 standard.

CONCLUSION:
All these elements show the safety and effectiveness of our product. Our titanium Telegraph humeral nails are substantially equivalents to the Telegraph humeral nail cleared in K033510 in terms of intended use, design, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Christine Quendez
Regulatory Affairs Manager
Fournitures Hospitalieres Industrie
6 Rue Nobel, Z.I. de Kernevez
29000 Quimper-France

Re: K042332
Trade/Device Name: Titanium TELEGRAPH® Humeral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: August 23, 2004
Received: August 30, 2004

Dear: Ms Quendez

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.

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 (240) 276-0120. 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,

for 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

510(k) Number (if known): K042332

Device Name: Titanium TELEGRAPH® Humeral Nail

Indications for Use: The TELEGRAPH® Humeral Nail is indicated for fractures of the upper extremity and/or the diaphysis of the humerus.

Mark N Millerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042332

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over the counter Use ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)