K052058

AUG 2 2 2005

# 510 (K) SUMMARY – Titanium TELEGRAPH® HUMERAL NAIL

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

**SUBMITTER:**

Fournitures Hospitalières Industrie
6 Rue Nobel, Z.I. de Kernevez
29000 QUIMPER, France

**COMPANY CONTACT:**

C.Quendez
Regulatory Affairs Manager
Phone number: 33.2.98.55.68.95
Fax number: 33.2.98.53.42.13

**DATE PREPARED:** July 27th 2005

**DEVICE NAME:**

| | |
|---|---|
| **Trade Name:** | Titanium TELEGRAPH® HUMERAL NAIL |
| **Common name:** | Humeral Nail |
| **Classification name:** | Intramedullary Rod |

**PREDICATE DEVICES:**

Titanium TELEGRAPH® HUMERAL NAIL
Fournitures Hospitalieres Industrie
K042332

TELEGRAPH® HUMERAL NAIL.
Fournitures Hospitalieres Industrie
K033510

**DEVICE DESCRIPTION :**

The Titanium Telegraph® Humeral Nail is designed to be inserted in the proximal extremity of the humerus. It is made of titanium (according to ASTM 136) and is available in two models: the short humeral nail (150mm) and the long humeral nail (from 210 to 310mm). All models are available in three diameters (7, 8, 9 and 10mm). These two Humeral Nail are intended to be used with cancellous screws and self-threating cortical cotter screws, supplied by FH Industrie.

This special 510(k) is being submitted to propose clearance of the titanium self-threating cortical cotter screws intended to be used with the Titanium Telegraph® Humeral Nail cleared in k042332. FH Industrie will manufacture and commercialize these screws.

These screws are made of titanium (according to ISO 5832 and ASTM F-136) and are available in 4 lengths (24, 28, 30, 32mm) and with a 4mm diameter.

**INTENDED USE :**

The titanium Telegraph® humeral nail is indicated for proximal and/or diaphyseal fractures of the humerus

**TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICES :**

The proposed Titanium Telegraph® Humeral nail is now provided with sterile cancellous screws and sterile self-threating cortical cotter screws. It has exactly the same intended use and same design as the predicate devices. No change was made on the design and material and of the humeral nail. Diameters and lengths remain unchanged.
The main difference between the new and the previous devices is that these self-threating cortical cotter screws will be manufactured in titanium and supplied with the device. The screws are all made of the same material (titanium), have the same design and are available in similar diameters and lengths.

**PERFORMANCE DATA:**

Risk to health have been addressed through the specified materials, Processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

**CONCLUSION:**

All these elements show the safety and effectiveness of our product.
The titanium Telegraph® Humeral Nail is substantially equivalent to the selected predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Ms. Christine Quendez
Regulatory Affairs Manager
Fournitures Hospitaliéres Industrie
ZI de Kernevez, 6 Rue Nobel
29000 Quimper, France

Re: K052058
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: July 27, 2005
Received: August 3, 2005

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

Mark N. Melkerson
Acting 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): K052058

Device Name: TITANIUM TELEGRAPH HUMERAL NAIL

Indications for Use: The titanium Telegraph humerail nail is indicated for proximal and/or diaphyseal fractures of the humerus

Prescription Use ___X___ AND/OR Over the counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brietzman for MK

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

**510(k) Number** K052058