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510 (K) SUMMARY – TELEGRAPH® Humeral Nail

Submitter name: Fournitures Hospitalières Industrie

Submitter address: 6 Rue Nobel, Z.I. de Kernevez
QUIMPER, France 29000

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Date prepared: September 20, 2002

Device Trade Name: Telegraph® Humeral Nail

Device common name: Humeral Nail

Classification name: Intramedullary fixation rod

Predicate Devices: **Polarus**
Acumed Inc.
K 951740

Fixion™ Intramedullary Nailing System
Disc-O-Tech Medical Technologies, Inc.
K 010901

Device description: The Telegraph® Humeral nail is designated to be inserted in the proximal extremity of the humerus. It is constructed from stainless steel (ISO 5832/1), length 150 mm for the short humeral nail or 210 to 310 mm length for the long humeral nail, all models are available in three diameters : 7, 8 and 9 mm. It has three proximal and two distal holes for 4.0 mm diameter, fully-threaded screws suitable for cancellous fixation of small bone fragments.
The two distal holes can if necessary be used for locking. But its advantages result mainly from the possibilities afforded by the three proximal screwholes.

Intended use: Telegraph® Humeral nail with locking screws is intended to be used for proximal and/or diaphyseal fractures of the humerus.

Device Technological Characteristics and Comparison to Predicate Devices: The Telegraph® Humeral Nail has the same intended use, is made of the same material, is available in similar diameters and lengths, and has a similar design as the predicate devices.

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Performance Data:

Performance characteristics of Telegraph® Humeral nail have been tested and approved through mechanical test according to standard ASTM.F-1264: Standard Specification and Test Methods for Intramedullary Rods. Moreover, verification, validation and design control activities demonstrate the safety and effectiveness of the Telegraph® Humeral Nail.

Conclusion:

The Telegraph Humeral Nail is substantially equivalent to predicate device in terms of intended use, safety, and effectiveness.



DEC 24 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fournitures Hospitalieres Industrie
c/o M. Frank Lewis
President
InnerVision, Inc.
6258 Shady Grove Road East
Memphis, Tennessee 38120

Re: K023241

Trade/Device Name: Telegraph Humeral Nail
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 5, 2002
Received: September 30, 2002

Dear Mr. Lewis:

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

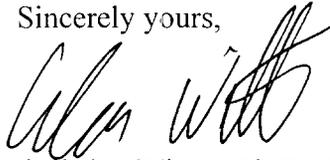
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the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 (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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

INTENDED USES / INDICATIONS

510 K Number (if known): K023241

Device Name: TELEGRAPH® Humeral Nail With Locking Screws

Indications For Use: Telegraph® Humeral nail is indicated for proximal and/or diaphyseal fractures of the humerus.

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

510(k) Number K023241