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K ...030665.....

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE OF APPLICATION: 2003-02-21

Submitted by:: Störk Instrumente GmbH
Engener Straße 29
D-78576 Emmingen/Liptingen
Germany
Tel.: +49 (7465) 825
Fax: +49 (7465) 2216

1. DEVICE DESCRIPTION

Trade Name: Bone Wire
Common Name: Kirschner Wire (K wire), Steinmann Wire, Bonell Wire (Pin), Cerclage Wire

2. CLASSIFICATION

Device:	Pin, Fixation Smooth	Pin, Fixation, Threaded
Medical Specialty:	Part 888, Orthopedic	Part 888, Orthopedic
Product Code:	87 HTY	87 JDW
Device Class:	2	2
Regulation Number:	888.3040	888.3040

3. INTENDED USE

The intended use of Störk Instrumente GmbH's Bone Wires is the fixation of bone fractures and / or to guide other implants during insertion to the skeletal system.
Due to their design and used materials, which is either Stainless Steel acc. ASTM F 138 / 139 (316 L) or Titanium Alloy acc. to ASTM F 136, Grade 5, these devices can be used as implants.
Störk Instrumente GmbH is offering their Bone Wires only in an Non-Sterile condition.

4. Substantial Equivalence

Störk Instrumente GmbH's Bone Wires are substantially equivalent to other Bone Wires e.g. Kirschner Wires or Steinmann Pins legally marketed by many companies including

- Syntec-Taichung Co., Ltd., #K983121
- Osteonics Corporation, #K971862
- DePuy Inc., #K960385
- Synvasive Technology Inc., #961522

5. Biocompatibility

The biocompatibility is guaranteed by the composition of the used materials as mentioned in chapter 6. These materials are also used for most other surgical implants as bone screws, bone plates or neuro surgical implants as Aneurysm Clips as mentioned in following 510(k)'s:

- K983758, Aesculap AG, Aesculap Yasargil Titanium Aneurysm Clips;
- K000080, Howmedica Osteonics Corp., Asnis III Cannulated Screw System;
- K003500, Rebstock Instruments GmbH, Rebstock Yasargil Aneurysm Clips.

Störk Instrumente GmbH's Bone Wires are only made out of the in chapter 6 mentioned Raw Materials.

Compared with competitors Störk Instrumente GmbH's Bone Wires are made out of similar materials.

6. Sterilization by User

Störk Instrumente GmbH delivers all Bone Wires in Non-Sterile conditions. The user may sterilize these devices by using a validated and applicable sterilization process.

Störk Instrumente GmbH recommends to use a steam-sterilizer that uses a validated sterilization cycle of 134°C / 270°F, 3 bar, for 10 minutes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

Störk Instrumente GmbH
c/o Ms. Lori Advids
Independent Import Agent Service LLC
Subsidiary of the Hirdes Group
7046 Bentley Drive
Gurnee, IL 60031

Re: K030665
Trade/Device Name: Bone Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: February 21, 2003
Received: March 3, 2003

Dear Ms. Advids:

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.

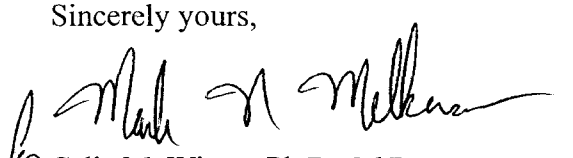
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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

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IFU-STATEMENT

INDICATION FOR USE

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for Mark N Melkerson

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

510(k) Number K030665