JUL 14 2003

K031050

510(k) Premarket Notification Summary of Safety Information	***PCW™ Percutaneous Compression Wire*** January 12, 2003

Device Name:

Trade Name: ***PCW™ Percutaneous Compression Wire***
Common Name: k-wire
Classification Name: Smooth & threaded metallic bone fixation fasteners

Establishment Name & Registration Number:

Name: Millennium Medical Technologies, Inc. (MMT)
Number: 1724527

Classification:

ProCode: HWC

Performance Standards (Section 514 compliance):

Food and Drug Administration mandated Performance standards for bone screws are not in effect. MMT intends to comply with all voluntary Performance Standards applicable to the ***PCW™ Percutaneous Compression Wire*** system. At the present time, The device is produced according to ISO 9001-2000 regulations covering medical devices. In addition, the materials used to construct the device meet ISO-5832-3,1996(E).

Special Controls:

All Class II devices are subject to Special Controls. No FDA mandated special controls are in effect for this device at the present time.

Labeling:

The labeling of the device includes the following statements:

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician only.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other material composition. Components of the ***PCW™ Percutaneous Compression Wire*** should NOT be used with screws or components from any other system or manufacturer.

Equivalent Device(s):

PCW™ Percutaneous Compression Wire may be directly contrasted with the following equivalent devices:

- ***Synvasive k-wires,*** Synvasive Technology, Inc., *K961522*
- ***Miltex Steinmann pins,*** *Miltex, Inc. K013888*

Both referenced devices are essentially identical (clinically speaking) to the ***PCW™ Percutaneous Compression Wire*** in terms of basic design, features and intended use.

Description of the Device:

The ***PCW™*** is supplied as a single length threaded stainless steel wire or pin. The pin is self-tapping and self-cutting and does not vary in length or diameter. The engineering drawings include diameter and length information. However, the pins are nominally six inches in length and fifty-nine thousandths diameter. The pins are intended for small bone applications (fractures and osteotomies) including distal fragments of long bones. The principal areas of use are the upper extremity and the hands and feet. The pins may be used for selected fractures elsewhere in the body so long as medically indicated and bone

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mass compatible. The primary use of the wires is percutaneous, that is, without the need for an external fixatior as in the case of "hammer-toes" or similar phlangeal or small bone osteotomies. The secondary use of the wires is in association with the use of an external fixation device as a means to secure and fix small fragments until healing is complete. MMT supplies instrumentation designed specifically to interface with this implant system. Their use of general manual orthopaedic instrumentation is not recommended for the insertion of this device. The screws are made from stainless steel alloy. Material standard(s) are as specified in the table below:

316 LVM	ASTM F138, Gr. 2	ISO 5832-1

The instruments are made from 17-4 instrument grade stainless steel.

Instrumentation/accessories:

- Compression Wires (5 sizes)
- Compression nut
- Locking nut
- Socket wrench
- PCW Tray

Intended Use:

- Scaphoid fractures
- Lunate fractures
- Capitate
- Carpal fractures & non-unions
- Capitellum fractures
- Humeral head fractures
- Trapezial fractures
- Metacarpal and metatarsal fractures
- Phalangeal fractures
- Distal radial fractures
- Ulnar styloid fractures
- Osteo-chrondral fractures
- Small joint fusions
- Glenoid fractures
- Intercarpal fusions
- Interphalangeal fractures
- Metatarsal osteotomies
- Tarsal fusions
- Malleolar fractures
- Hammer toe fixation

Applicant / Sponsor Name / Address:

Millennium Medical Technologies, Inc.
460 St. Michaels Drive, Suite 901
Santa Fe, New Mexico, 87505
505.988.7595 – 505.988.7234 fax

Contact Person:

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Millennium Medical Technologies, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

JUL 14 2003

Re: K031050
Trade/Device Name: PCW™ Percutaneous Compression Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 26, 2003
Received: June 13, 2003

Dear Mr. Schlerf:

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,

Miriam C. Provost

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

510(k) Number (if known): K031050

Device Name: ***PCW™ Percutaneous Compression Wire***

Indications For Use:

Percutaneous Compression Wire system for the fixation of osseous fragments or fractures of small bones, including:

- Scaphoid fractures
- Lunate fractures
- Capitate
- Carpal fractures & non-unions
- Capitellum fractures
- Humeral head fractures
- Trapezial fractures
- Metacarpal and metatarsal fractures
- Phalangeal fractures
- Distal radial fractures
- Ulnar styloid fractures
- Osteo-chrondral fractures
- Small joint fusions
- Glenoid fractures
- Intercarpal fusions
- Interphalangeal fractures
- Metatarsal osteotomies
- Tarsal fusions
- Malleolar fractures
- Hammer toe fixation

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K031050

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)