K046756-S1 1/2

JUL 1 4 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Hedrocel Trabecular Metal Reconstructive System

Submitter Name	Implex Corp.
And Address:	80 Commerce Drive, Allendale, New Jersey 07401-1600
Contact Person:	Marci Halevi
Phone Number:	(201) 818 - 1800, X 507
Fax Number:	(973) 829 - 0825
Date Prepared:	March 19, 2004
Device Trade Name:	The Trabecular Metal Reconstructive System
Device Common Name:	Surgical Mesh
Classification Number and Name:	21 CFR § 878.3300 Surgical Mesh

Substantial Equivalence:

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Device Description:

The *Trabecular Metal Reconstructive System* is manufactured wholly of Trabecular Metal porous tantalum, the same material that comprises numerous medical devices intended for use in orthopedic applications. Trabecular Metal porous tantalum is 80% porous with fully interconnecting pores that are about 0.5mm in diameter.

The components of this line extension are wedge-shaped components, similar to the cleared wedge-shapes (K032344). The smallest size wedge is 19mm height with a 5° angle and the largest size wedge is 28mm height with a 30° angle. The angles run in increments of 5 degrees and there are 6 heights for each range of angles. One 'arm' is longer than the other, with the shorter 'arm' contoured along its length and slightly wider than the longer 'arm'. The base of the wedge is contoured. The relief allows biological fixation to occur along both the outer and inner segments of the device.

510(K) Summary Of Safety And Effectiveness – con't

MATERIALS: Tantalum (Hedrocel porous tantalum)

Indications for Use:

The *Trabecular Metal Reconstruction System* is indicated for use in reinforcing weak and/or deficient bony tissues in orthopaedic surgical procedures, such as pelvic reconstruction, acetabular reconstruction, cement restriction and in long bone procedures such as femoral and humeral reconstruction. When used in long bone procedures, ancillary fixation, such as plates and screws, must be used. The Trabecular Metal Reconstruction system may be used with bone graft.

Device Technological Characteristics & Comparison to Predicate Device:

A comparison of device technological characteristics and properties demonstrates that the device is substantial equivalent to the cited predicate devices.

Performance Data:

The subject devices of the Trabecular Metal Reconstructive System were not tested. Rather previous device testing per FDA guidance documents and applicable standards were performed for the predicate devices described in K02388, Master File MAF #920, and other mechanical testing reported in K962468. These results indicate that the subject device will perform as indicated for use in support of weakened and/or deficient bony structures.

Conclusion:

The *Trabecular Metal Reconstructive System* is substantially equivalent to the cited predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 4 2004

Marci Halevi
Manager of Regulatory Affairs
Implex Corp.
80 Commerce Drive
Allendale, New Jersey

Re: K040756
Trade/Device Name: Trabecular Metal Reconstruction System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM, EZX
Dated: March 23, 2004
Received: March 24, 2004

Dear Ms. Halevi:

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 Mark N. Melkerson

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): K040756 -S1

Device Name: **The Trabecular Metal Reconstruction System**

Indications For Use:

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

510(k) Number K040756

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR... Over-The-Counter Use _____

(Optional Format 1-2-96)