NOV 19 2003

K033384

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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, ext. 507
Fax Number:	(973) 829 - 0825
Date Prepared:	October 21, 2003
Device Trade Name:	The Hedrocel Trabecular Metal Reconstructive System
Device Common Name:	Surgical Mesh
Classification Number and Name:	21 CFR § 878.3300 Surgical Mesh

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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 *Hedrocel Trabecular Metal Reconstruction System* is manufactured wholly of Hedrocel porous tantalum. Hedrocel porous tantalum is 80% porous with fully interconnecting pores that are about 0.5mm in diameter. This line extension adds new components to the *Hedrocel Trabecular Metal Reconstruction System.*

MATERIALS: Tantalum (Hedrocel porous tantalum)

510(k) Summary Continued...

Indications for Use:

The Hedrocel 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 Hedrocel Trabecular Metal Reconstruction System may also 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 *Hedrocel Trabecular Metal Reconstructive System* was tested per FDA guidance documents and applicable standards for K010378, as referenced in the predicate K023882, K032282 and K032344. In addition, mechanical test data found in MAF #920 and K962468, and calculations found herein indicate the subject Hedrocel porous tantalum devices possess sufficient strength for the indicated use. These results indicate that the subject device will perform as indicated for use in support of weakened and/or deficient bony structures.

Conclusion:

The *Hedrocel 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

NOV 1 9 2003

Ms. Marci Halevi
Manager of Regulatory Affairs
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K033384
Device Name: Hedrocel Trabecular Metal Reconstruction System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: October 21, 2003
Received: October 23, 2003

Dear Ms. Halevi:

We have reviewed your Section 510(k) pre-market notification of intent to market the device referenced above and we 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 (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

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.

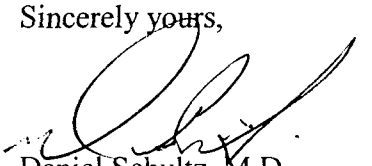
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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" (21CFR 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,



Daniel Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1-11

510(k) Number (if known): K033384

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

Indications For Use:

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Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K033384

(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) OR... Over-The-Counter Use _____

(Optional Format 1-2-96)