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K032344

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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, X 507
Fax Number:	(973) 829 - 0825
Date Prepared:	September 3, 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

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

The devices in this line extension are wedge shaped and contoured so as to fit a variety of anatomical bone structures. The devices are available in small, medium and large sizes, with the cross-sectional dimensions being 0.52in x 0.88in for the small size; 0.58in x 0.96in for the medium size, and 0.62in x 1.06in for the large size. Each size consists of varying heights ranging from 2mm - 8mm in 2mm increments. There is a consistent inclination angle of 10 degrees along the length in all size ranges. A secondary inclination angle along the width ranges from 20-35 degrees in 5-degree increments. The resultant geometry is a bi-plane wedge. The devices have a 6mm central hole for optional bone graft placement. A tapered slot is provided for implantation instrumentation.

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

MATERIALS: Tantalum (Hedrocel porous tantalum)

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 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 device of the Hedrocel Trabecular Metal Reconstructive System was not tested. Rather previous device testing per FDA guidance documents and applicable standards were performed for the predicate devices described in K023882 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 *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

OCT - 2 2003

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

Re: K032344
Trade/Device Name: The Hedrocel Trabecular Metal Reconstruction System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: EZX
Dated: September 3, 2003
Received: September 4, 2003

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): K032344

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

Indications For Use:

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

510(k) Number K032344 10/1/03

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

(Optional Format 1-2-96)