JUL 17 2002

K02/967

page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Hedrocel Vertebral Body Replacement System

Submitter Name And Address:	Implex Corp. 80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert A Poggie, PhD
Phone Number:	(201) 818-1800
Fax Number:	(973) 829-0825
Date Prepared:	June 14, 2002
Device Trade Name:	Hedrocel Vertebral Body Replacement System
Device Common Name:	Vertebral Body Replacement Device
Classification Number and Name:	21 CFR § 888.3060 Spinal Vertebral Body Replacement Device

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® Vertebral Body Replacement System is designed to be used as a replacement for a single diseased or damaged vertebral body and the adjacent disc when spinal surgery through an anterior approach is indicated.

The Hedrocel® Vertebral Body Replacement (VBR) System is comprised wholly of Hedrocel® Porous Tantalum (tantalum deposited on a vitreous carbon skeleton). The VBR is available to accommodate replacement of a vertebral body in the thoracic and lumbar region of the spine. The device is available in a variety of cross sections and heights to properly tension the spine.

The superior and inferior surfaces of the device have a pattern of ripples to provide increased stability. The Hedrocel® Vertebral Body Replacement implants have an included angle to maintain the natural contour of the lumbar spine.

The use of titanium or titanium alloy instrumentation is recommended.

K021967
Page 2 of 2

510(k) Summary (Continued)

Indications for Use:

The Hedrocel® Vertebral Body Replacement System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Hedrocel® Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Hedrocel® Vertebral Body Replacement may be used with bone graft.

Device Technological Characteristics and Comparison to Predicate Device:

The device is unique in comparison to predicates for this indication with regard to porous tantalum material and its structure. The material has been used in cited predicates for other applications.

Performance Data:

The Hedrocel Vertebral Body Replacement System was tested per applicable standards (reference K010378). Biocompatibility data was provided to support the material's use. Performance testing was provided to support equivalent mechanical behavior to the predicates. The results demonstrated that the device will perform as intended and is equivalent to the cited predicate devices. Test data was provided regarding:

- Static compression,
- Dynamic compression,
- Static torsion,
- Dynamic torsion, and
- Abrasion.

Conclusion:

The Implex Hedrocel Vertebral Body Replacement System is substantially equivalent to the following predicate devices identified in this premarket notification:

510(k) #	Product Name	Company
K010378 K021025	Hedrocel Vertebral Body Replacement	Implex Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Mr. Robert A. Poggie, PhD
Director of Applied Research
Implex® Corp.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K021967
Trade/Device Name: Hedrocel Vertebral Body Replacement System
Regulation Number: 21 CFR §888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 14, 2002
Received: June 17, 2002

Dear Dr. Poggie;

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.

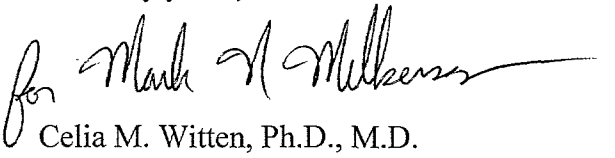
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

510(k) Number (if known): K021967

Device Name: The Implex Hedrocel Vertebral Body Replacement System

Indications For Use:

The Hedrocel® Vertebral Body Replacement System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Hedrocel® Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Hedrocel® Vertebral Body Replacement may be used with bone graft.

(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)

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

510(k) Number K021697