

**510(k) SUMMARY - Implex Cross-Linked Polyethylene
Acetabular Components**

Submitter Name: Implex Corp.

Submitter Address: 80 Commerce Drive
Allendale, New Jersey 07401-1600

Contact Person(s): Robert Poggie or John Schalago

Phone Number: (201) 818-1800

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Date Prepared: February 28, 2000

Device Trade Name: Implex Cross-Linked Polyethylene Acetabular Components

Device Common Name: Polyethylene Acetabular Components

Classification Name: Prosthesis, Hip, Acetabular Component, Cemented, Cementless

Predicate Devices: Implex Cross-Linked Polyethylene Acetabular Components are for use with the following legally marketed Implex devices:

- 1) The Implex HEP (Hedrocel) Acetabular Cup, cemented & cementless
- 2) The Implex Revision HEP (Hedrocel) Acetabular Cup, cemented & cementless
- 3) The Implex A-230 (beaded) Acetabular Cup System, cemented & cementless
- 4) The Implex Modular Elliptical Porous Cup System
- 5) The DePuy Duraloc Acetabular Cup System
- 6) Osteonics Cross-Fire Acetabular Components

510(k) Summary, Continued**Device Description:**

Implex Cross-Linked Polyethylene Acetabular Components are for use with the following legally marketed Implex devices with 28 mm femoral heads:

1. The Implex HEP (Hedrocel) Acetabular Cup, cemented & cementless. The permitted OD size is 52 mm and greater for the 0° face-angle, and OD sizes 50 mm and greater for the 10 and 20° face-angle options.
2. The Implex Revision HEP (Hedrocel) Acetabular Cup, cemented & cementless. The permitted OD size is 52 mm and greater for the 0° face-angle, and OD sizes 50 mm and greater for the 10 and 20° face-angle options.
3. The Implex A-230 (porous beads) Acetabular Cup System, cemented & cementless. The permitted OD size is 52 mm and greater for the 0°, 10° and 20° face angle options.
4. The Implex Modular Elliptical Porous Cup. The permitted OD size is 54 mm and greater for the 0°, 10° and 20° face angle options.

Intended Use:

The Implex Cross-Linked Polyethylene Acetabular Components are intended to be used with the above listed, legally marketed Implex Acetabular Component Replacement Systems to resurface the acetabular socket in cemented or cementless total hip arthroplasty.

Wear Claims:

Implex Cross-Linked Polyethylene Acetabular Components with sheet compression molded GUR 1020 show a 65% reduction in gravimetric wear rate versus the same acetabular components (28 mm/52 mm ID/OD, with polyethylene thickness of 9.5 mm) fabricated from Implex's current sheet compression molded GUR 1020 polyethylene, 47% less than the Charnley 'Gold Standard' (22 mm heads), and 87% less than the Charnley 'Gold Standard' 28 mm heads, (0.1 mm of linear head penetration converted to volumetric wear).

Wear Claims:

Implex Cross-Linked Polyethylene Acetabular Components with direct compression molded (DCM) GUR 1020 show a 89 % reduction in gravimetric wear rate versus the same acetabular components fabricated from Implex's current direct compression molded GUR 1020 polyethylene, 67 % less than the Charnley 'Gold Standard' (22 mm heads), and 95 % less than the Charnley 'Gold Standard' 28 mm heads), (0.1 mm of linear head penetration converted to volumetric wear).

ps 3.0.3

All hip wear simulation testing was performed under multi-axial hip joint simulation for 5 million cycles, using a super-finished Implex 28 mm Co-Cr-Mo femoral head articulating counterface, a polyethylene component corresponding to a shell OD of 52 mm, and with bovine calf serum as a lubricant. Polyethylene thickness was 8.2 mm for the tested DCM components.

The results of such *in-vitro* hip wear simulation tests have not been shown to correlate with clinical wear mechanisms.

**Statement of
Technological
Comparison:**

The intended use, indications, contraindications, and design specifications of the subject components remain the same as their Implex predicate component counterparts, for the acetabular components and sizes listed above. The raw material being utilized in the manufacture of both the subject and predicate devices remains as direct and sheet compression molded ultra-high molecular weight polyethylene (UHMWPE) conforming to ASTM F-648. The modifications to the manufacturing process of this polyethylene will be introduced to create a higher cross-linked polyethylene.

The safety and effectiveness of this cross-linked polyethylene in acetabular applications, as well as the proposed wear claims, are supported by the substantial equivalence information, materials data and testing results provided within this Supplement #3 to K990330, the original 510(k) submission (K990330), and Supplements #1 and #2 to K990330.

Conclusion:

Implex Cross-Linked Polyethylene Acetabular Components are substantially equivalent to the above identified predicate devices and for the associated component sizes.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Robert A. Poggie
Director of Applied Research
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K990330
Trade Name: Cross-linked Polyethylene Acetabular Components
Regulatory Class: II
Product Code: JDI and LPH
Dated: December 2, 1999
Received: December 3, 1999

Dear Dr. Poggie:

We have reviewed your Section 510(k) 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 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

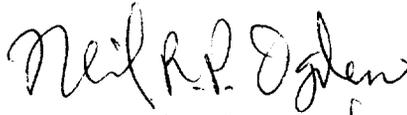
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

Page 2 - Dr. Robert A. Poggie

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Neil R. Dylow". The signature is written in a cursive style.

James E. Dillard III *for*
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990330

Device Name: Implex Cross-Linked Polyethylene Acetabular Components

Indications For Use: The Implex Cross-Linked Polyethylene Acetabular Components are intended to be used with the below listed, legally marketed Implex Acetabular Component Replacement Systems to resurface the acetabular socket in cemented or cementless total hip arthroplasty.

Implex Cross-Linked Polyethylene Acetabular Components are for use with the following legally marketed Implex devices with 28 mm femoral heads:

1. The Implex HEP (Hedrocel) Acetabular Cup, cemented & cementless. The permitted OD size is 52 mm and greater for the 0° face-angle, and OD sizes 50 mm and greater for the 10 and 20° face-angle options.
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3. The Implex A-230 (porous beads) Acetabular Cup System, cemented & cementless. The permitted OD size is 52 mm and greater for the 0°, 10° and 20° face angle options.
4. The Implex Modular Elliptical Porous Cup. The permitted OD size is 54 mm and greater for the 0°, 10° and 20° face angle options.

(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 801.106)

OR...

Over-The-Counter
Use

h/k
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

no Use h/k
K990330

(Optional Format 1-2-96)