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**Special 510(k) Summary - Device Modification**
**for the**
**Kinemax® All Polyethylene Patellar Component**
**to be marketed as**
**the Avon™ Patellar Component**

| | |
|---|---|
| **Proprietary Name:** | Avon™ Patellar Component |
| **Common Name:** | All Polyethylene Patellar Component |
| **Classification Name and Reference:** | 21 CFR 888.3540<br>Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prosthesis |
| **Proposed Regulatory Class:** | Class II |
| **Device Product Code:** | OR (87) KRR |

The Avon™ Patello-femoral Joint Replacement (found substantially equivalent in K010100) is intended to be used with the legally marketed Kinemax® Plus All Polyethylene Patellar Component in cemented replacement of the patello-femoral joint in patients with degenerative arthritis of the distal femur and patella, patients with a history of patellar dislocation or fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release).

It is the intention of Howmedica Osteonics Corp. to modify the Kinemax® Plus All Polyethylene Patellar Component. The modified device will be marketed as the Avon™ Patellar Component. This all polyethylene patellar component will be used to articulate with the cobalt-chromium alloy femoral component of the Avon™ Patello-femoral Joint Replacement.

The subject Avon™ Patellar Component is identical in design features with the exception of the following: a blend radius has been added on the articular surface of the patella in order to reduce the potential for impingement of the patellar component on the bone.

No other changes have been made to the design of the patellar component. The Avon™

Patellar Component will be available for use with bone cement in patello-femoral replacement surgery.

Design controls were utilized to identify the risks associated with the modified device. Testing was presented to address these risks. A Declaration of Conformity was included.

**For Information contact:**

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Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-2584
(201) 934-4359
Fax: (201) 760-8435

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2002

Mr. William J. Cymbaluk
Vice President, Quality Assurance/Regulatory Affairs/Clinical Research
Stryker Howmedica Osteonics
59 Route 17
Allendale, NJ 07401-1677

Re: K020841
Trade Name: Avon™ Patellar Component
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee Joint Patellofemoral Polymer/Metal Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KRR
Dated: March 14, 2002
Received: March 15, 2002

Dear Mr. Cymbaluk:

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,

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

## Indications for Use

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510(k) Number (if known): K020841

Device Name: Avon™ Patellar Component

Indications for Use:

The subject Avon™ Patellar Component is intended to be used with the Avon™ Patello-Femoral Joint Replacement in replacement of the patello-femoral joint. The subject Avon™ patellar component is a modification of the Kinemax® All Polyethylene Patellar Component. The Avon™ Patellar Component has been modified to include the addition of a blend radius on the medial aspect of the patella. This blend is designed to reduce the contact stress of the patella on the patello-femoral component. The rest of the design features of the Avon patellar component are identical to that of the previous released Kinemax® All Polyethylene Patellar Component.

The Avon™ Patello-femoral Joint Prosthesis is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Avon™ Patellar Component and the Avon™ Patello-femoral Joint Prosthesis are intended for use with bone cement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes OR Over-The-Counter Use No
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhaus
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020841