JUL 12 1999

K990135

P.O. Box 708
Warsaw, IN 46581-0708
219 267-6131

zimmer

Summary of Safety and Effectiveness

- **Submitted By:**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, Indiana 46581-0708
  219-267-6131

- **Contact Person:**

  Karen Cain
  Regulatory Affairs Associate
  Telephone: 219/372-4219
  Telefax: 219/372-4605

- **Date:**

  June 23, 1999

- **Trade Name:**

  Trilogy® Acetabular System *Longevity*® Crosslinked Polyethylene Liners

- **Common Name:**

  Acetabular Component for Hip Prosthesis

- **Classification Name:**

  Hip Joint Metal/Polymer/Metal Semiconstrained Porous-Coated Uncemented Prosthesis

- **Predicate Devices:**

  - *Trilogy*® Acetabular System, K934765, cleared April 29, 1994

Summary of Safety and Effectiveness
(Continued)

- *Trilogy*® Acetabular System, 36 mm Liners, K953490, cleared October 20, 1995

- *Trilogy*® Acetabular System, 7 mm Offset Liners, K954698, cleared January 17, 1996

- **Device Description**

The *Trilogy* Acetabular System *Longevity* Crosslinked Polyethylene Liners are modular, acetabular components of the same design, geometry, material, and intended use which was previously cleared in premarket notification K934765. This premarket notification contains wear test data of electron beam irradiated UHMWPE components to substantiate claims of improved wear properties due to the change in processing of the devices.

Trilogy Acetabular System *Longevity*® Crosslinked Polyethylene Liners showed an average 89 percent gravimetric wear reduction compared to the same cup conventionally gamma sterilized and both nonaged (final product after sterilization) and accelerated aged. The neutral liners (32 mm ID/48 mm OD, 5.3 mm thickness and 22 mm ID/36 mm OD, 4.3 mm thickness) were made from compression molded, calcium stearate free UHMWPE were highly crosslinked, thermal stabilized, then gas plasma sterilized both nonaged (final product after sterilization) and accelerated aged. All control and crosslinked liners that were accelerated aged were subjected to 73 psi of oxygen at 70°C for two weeks. Testing was performed to 5 million cycles using an AMTI hip simulator at 1 Hz, a cobalt-chrome articulating counterface, and bovine serum as lubricant. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

Trilogy Acetabular System *Longevity* Crosslinked Polyethylene Liners showed an average 89 percent gravimetric wear reduction compared to the same cup conventionally gamma sterilized and accelerated aged when evaluated under abrasive wear conditions. The neutral liners (32 mm ID/48 mm OD, 5.3 mm thickness and 22 mm ID/36 mm OD, 4.3 mm thickness) were made from compression molded, calcium stearate free UHMWPE were highly crosslinked, thermal stabilized, and gas plasma sterilized. The liners were subjected to accelerated aging. Testing was performed to 3 million cycles using a Shore Western orbital-type hip simulator at 1Hz, a cobalt-chrome articulating counterface, and bovine serum as lubricant. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

Zimmer highly crosslinked, thermally stabilized UHMWPE, in both accelerated

aged and nonaged (final product after sterilization) conditions, was evaluated by Electron Spin Resonance (ESR) spectroscopy to determine residual free radicals. The experimental detection limit is estimated to be 10^{13} spins/gram. In all cases, the residual free radical content was undetectable. Reduced levels of free radicals are associated with decreased oxidation of the material.

- **Intended Use**

  The *Trilogy* Acetabular System *Longevity* Crosslinked Polyethylene Liners are intended to be used with *Trilogy* Acetabular Shells and *Zimmer* femoral stems and heads in cemented or uncemented use in total hip arthroplasty.

- **Comparison to Predicate Devices**

  The predicate devices listed above are substantially equivalent to each other and the *Trilogy* Acetabular System *Longevity* Crosslinked Polyethylene Liners in that each is a component of a system that is intended to be implanted into the human acetabulum. All predicate devices and the new device are manufactured from UHMWPE which serves as the articulating bearing surface for the femoral component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Karen Cain
Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K990135/S1
Trade Name: *Trilogy®* Acetabular System *Longevity®* Crosslinked Polyethylene Liners
Regulatory Class: II
Product Code: LPH
Dated: May 5, 1999
Received: May 7, 1999

Dear Ms. Cain:

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 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 (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.

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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit AA

510(k) Number (if known K990135

Device Name: *Trilogy*® Acetabular System *Longevity*® Crosslinked Polyethylene Liners

Indications for Use:

The *Trilogy*® Acetabular System is indicated for either cemented or noncemented use in skeletally mature individuals undergoing surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

See Next Page for Wear Claims

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

RA01901K.510.DOC

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990135

WEAR CLAIMS

Trilogy Acetabular System *Longevity*® Crosslinked Polyethylene Liners showed an average 89 percent gravimetric wear reduction compared to the same cup conventionally gamma sterilized and both nonaged (final product after sterilization) and accelerated aged. The neutral liners (32 mm ID/48 mm OD, 5.3 mm thickness and 22 mm ID/36 mm OD, 4.3 mm thickness) were made from compression molded, calcium stearate free UHMWPE were highly crosslinked, thermal stabilized, then gas plasma sterilized both nonaged (final product after sterilization) and accelerated aged. All control and crosslinked liners that were accelerated aged were subjected to 73 psi of oxygen at 70°C for two weeks. Testing was performed to 5 million cycles using an AMTI hip simulator at 1 Hz, a cobalt-chrome articulating counterface, and bovine serum as lubricant. The results of *in vitro* tests have not been shown to correlate with clinical wear mechanisms.

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RA01901K.510.DOC

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990135

Prescription Use X
(Per 21 CFR 801.109)