DEC 17 1998 K982981

zimmer

P.O. Box 708
Warsaw, IN 46581-0708
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Summary of Safety and Effectiveness
New *Zimmer* Shoulder System

- **Submitted by**

  Zimmer, Inc.
  P.O. Box 708
  Warsaw, IN 46581-0708

- **Prepared by**

  Laura D. Williams
  Specialist
  Regulatory Affairs
  Telephone: 219-372-4523
  Fax: 219-372-4605

- **Date**

  August 25, 1998

- **Trade Name**

  New *Zimmer*® Shoulder System

- **Common Name**

  Shoulder Prosthesis

- **Classification Name**

  Shoulder Joint Metal/Polymer Nonconstrained Cemented Prosthesis

- **Substantial Equivalence Summary**

  The New *Zimmer* Shoulder System utilizes design features common to one or more of the following devices:

Device	K Number(s)	Decision Date
Fenlin Total Shoulder	K852137	2/12/86
Fenlin RCD Total Shoulder	K870262	4/3/87
Zimmer Total Shoulder II	K790987	6/22/79
3-M Neer II Shoulder Prosthesis	K895226	11/3/89

Summary of Safety and Effectiveness
New *Zimmer* Shoulder System
(Continued)

Device	K Number(s)	Decision Date
3-M Modular Shoulder System	K920362	7/22/93
Osteonics Shoulder Components	K955731 K962082	3/5/96 8/13/96
Kirschner Modular II-C Total Shoulder System	K940537	8/29/95
Intermedics Select Shoulder	K962315 K962238	9/3/96 8/9/96
DePuy Global Total Shoulder	K914695	1/16/92

- **Device Description**

The New *Zimmer* Shoulder features modular and monoblock cobalt-chrome alloy humeral stems intended for use with or without cement in total shoulder arthroplasty. The cobalt-chrome alloy humeral heads feature female Morse-type tapers which facilitate assembly with the modular humeral stems. The keeled glenoid component is manufactured from UHMWPE. It is intended for cemented use only.

- **Intended Use**

This prosthesis is intended to be implanted to replace a shoulder joint.

Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; ununited humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable.

The components of the New *Zimmer* Shoulder System are intended for single use only. The glenoid component is designed for cement fixation only; the humeral stem may be implanted by press-fit or cement fixation.

Summary of Safety and Effectiveness
New *Zimmer* Shoulder System
(Continued)

- **Performance Testing**

  Testing performed on the taper and the glenoid component demonstrated that the New *Zimmer* Shoulder System is safe and effective and substantially equivalent to predicate devices.

  RA07801K.510.D0C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 1998

Ms. Laura D. Williams
Specialist, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K982981
Trade Name: The New Zimmer® Shoulder System
Regulatory Class: III
Product Codes: KWT and HSD
Dated: August 25, 1998
Received: August 26, 1998

Dear Ms. Williams:

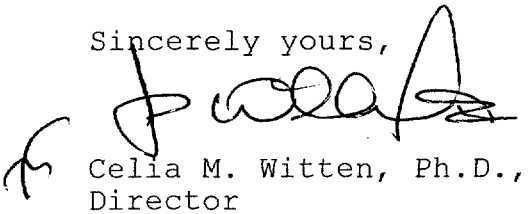
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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

510(k) Number (if known): K982981

Device Name: New *Zimmer* Shoulder System

Indications For Use:

Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; ununited humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional nonconstrained arthroplasty is not acceptable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982981

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

RA07801K.510