JAN 16 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Stephen McKelvey Manager, Regulatory Affairs Telephone: (574) 372-4944 Fax: (574) 372-4605
Date:	October 17, 2003
Trade Name:	Zimmer Unicompartmental Knee System
Common Name:	Unicompartmental Knee
Classification Name and Reference:	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, 21 CFR § 888.3520
Predicate Device:	The predicate devices for the Zimmer Unicompartmental Knee System are the Miller/Galante Precoat Unicompartmental Knee System, K880155 (cleared 8/3/88) and the Miller/Galante Precoat Unicompartmental Knee System (8 mm Articular Surface) Line Extension, K010685 (cleared 4/2/01).
Device Description:	The Zimmer Unicompartmental Knee System (Zimmer Uni) is a prosthesis that replaces only one compartment of the knee condyles. It is unconstrained in the anteroposterior and mediolateral directions and also allows unconstrained internal/external rotation between the femoral and tibial components. This movement is limited only by the ligaments and other soft tissues surrounding the device.
Intended Use:	These devices are indicated for patients with: - Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.

- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
- Revision of previous arthroplasty procedures.

These devices are indicated for cemented use only.

The Zimmer Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.

Comparison to Predicate Device:

The Zimmer Unicompartmental Knee System is substantially equivalent to the Miller/Galante Precoat Unicompartmental Knee System in that both have similar indications, design (both are non-constrained, unicompartmental knee prostheses), materials and mechanical safety. Both devices are intended for cemented use only.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Performance testing completed as part of the design assurance procedure for the Zimmer Unicompartmental Knee System and FMEA demonstrated that this device is safe and effective and substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2004

Mr. Stephen McKelvey
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K033363
Trade/Device Name: Zimmer Unicompartmental Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint Femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSX
Dated: October 17, 2003
Received: October 21, 2003

Dear Mr. McKelvey:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

Enclosure

K033363

Indications for Use

510(k) Number (if known): K033363

Device Name:

Zimmer Unicompartmental Knee System

Indications for Use:

These devices are indicated for patients with:

- Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis.
- Previous tibial condyle or plateau fractures with loss of anatomy or function.
- Varus or valgus deformities.
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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...sion Sign-Off)
...ivision of General, Restorative
...d Neurological Devices

...(k) Number K033363