K061882 (pg 1 of 3)

AUG 0 1 2006

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Mason W. Robbins Regulatory Affairs Specialist Telephone: (574) 371-8065 Fax: (574) 372-4605
Date:	June 30, 2006
Trade Names:	Apollo® Knee System APR® Hip System Bipolar Prosthesis Epsilon™ Acetabular System MOST® System Natural-Knee® System Natural-Knee® II System
Common Names:	Total Knee Prosthesis, Articulating Surface Unicondylar Knee Prosthesis, Articulating Surface Total Hip Prosthesis, Bipolar Prosthesis Total Hip Prosthesis, Acetabular Articulating Surface
Classification Names and References:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3560 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR 888.3353 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis, 21 CFR 888.3390 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR 888.3358 Hip joint metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3350

	Knee joint femorotibial metal/polymer constrained cemented prosthesis, 21 CFR 888.3510 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis, 21 CFR 888.3530 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis, 21 CFR 888.3535
Predicate Devices:	All standard ultra high molecular weight polyethylene (UHMWPE) components of the following legacy Centerpulse trade names: Apollo® Knee System APR® Hip System Bipolar Prosthesis Epsilon™ Acetabular System MOST® System Natural-Knee® System Natural-Knee® II System
Device Descriptions:	All standard UHMWPE components of the following legacy Centerpulse trade names: Apollo® Knee System APR® Hip System Bipolar Prosthesis Epsilon™ Acetabular System MOST® System Natural-Knee® System Natural-Knee® II System
Intended Uses:	Indications for use of the proposed devices will not change from the indications for use as described in their respective predicate device 510(k) submissions.
Comparison to Predicate Devices:	The proposed devices are identical to the predicate devices. The packaging for the legacy Centerpulse standard UHMWPE devices will be changed from the current packaging to the packaging used for legacy Zimmer, Inc. UHMWPE device in order to standardize packaging within Zimmer, Inc.
Performance Data (Non-clinical and/or Clinical):	Non-clinical Performance and Conclusions: Package configurations for legacy Zimmer Inc. and legacy Centerpulse were compared for levels of

K061882 (p3 of 3)

residual oxygen and surface oxidation index in standard polyethylene devices after long-term shelf-life aging. The legacy Zimmer Inc. nitrogen-flushed package outperformed the legacy Centerpulse package containing an oxygen absorber. Surface oxidation was not detected on any of the samples, regardless of package configuration. The legacy Zimmer Inc. nitrogen-flushed package for standard polyethylene devices is sufficient for use for packaging of legacy Centerpulse standard polyethylene inserts.

Zimmer Inc. does not believe clinical data are needed in support of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

Zimmer, Inc
% Mason W. Robbins, MS, RPCV, CCRP
Regulatory Affairs Specialist
P.O. Box 708
Warsaw, Indiana 46581

Re: K061882
Trade/Device Name: Oxygenless Packaging Conversion of Legacy Centerpulse Standard Polyethylene Devices
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MEH, LPH, JDI, KWY, KRO, HRY, NJD, LZO
Dated: June 30, 2006
Received: July 3, 2006

Dear Mr. Robbins:

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.

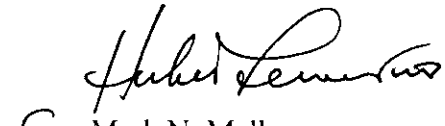
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061882

Indications for Use

510(k) Number (if known):

Device Name:

Oxygenless Packaging Conversion of Legacy Centerpulse Standard Polyethylene Devices

Trade Names:
Apollo® Knee System
APR® Anatomical Hip System
Bipolar Prosthesis
Epsilon™ Acetabular System
MOST® System
Natural-Knee® System
Natural-Knee® II System

Indications for Use:

Indications for use of the proposed devices will not change from the indications for use as described in their respective predicate device 510(k)s; only a change in packaging is being proposed.

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)

Helen Lemen

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number k061882