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Summary of Safety and Effectiveness

APR 26 2007

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Anthony Francalancia, RAC Senior Associate, Regulatory Affairs Telephone: (574) 372-4570 Fax: (574) 372-4605
Date:	April 9, 2007
Trade Name:	*Durom*® Hip Resurfacing System, Femoral Components
Common Name:	Prosthesis, hip, femoral, resurfacing
Classification Name and Reference	Hip joint femoral (hemi-hip) metallic resurfacing prosthesis 21 CFR § 888.3400
Device Product Code and Panel Code:	Orthopedics/87/KXA
Predicate Devices:	Cemented Femoral Head Resurfacing Device, manufactured by Biomet Orthopedics, K021799, cleared June 26, 2002. DePuy ASR™ Resurfacing Femoral Heads, manufactured by DePuy Orthopaedics, K032659, cleared December 4, 2003. BIOPRO TARA Femoral Resurfacing Component, manufactured by BioPro, Inc., K043542, cleared May 18, 2005. The Cormet 2000 Hemi Hip Metallic Resurfacing Prostheses, manufactured by Corin Medical, K994153, cleared February 25, 2000.
Device Description:	The *Durom*® Hip Resurfacing System femoral component consists of a monoblock head and slim-line femoral guide pin. The head is an extended hemisphere (greater than 180°). It is available in 12 sizes with Outside Diameters (ODs) ranging from 38mm to 60mm. The sphericity of the head is tightly controlled to less than 10 microns. The

underside of the head has recesses for controlled pressurization of cement into the cancellous bone, and for rotational stability after implantation.

Intended Use:

FOR HEMI-HIP RESURFACING ARTHROPLASTY:

The Durom Hip Resurfacing system femoral component, when used for hemi-hip arthroplasty, has been designed for cemented use in patients who are likely to outlive a conventional hip prosthesis. Femoral hip resurfacing hemi arthroplasty is most appropriate for patients with good bone quality in the femoral head and acetabulum, where the bearing surface and supportive bone structure of the acetabulum is normal, and where acetabular replacement is neither required nor desirable. Such patients will generally be under the age of 65.

- Non inflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis if remaining bone stock is adequate, and osteoarthritis
- Inflammatory joint disease (IJD), e.g. rheumatoid arthritis
- Joint replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives

Additional indications include other abnormalities where major pathology affects the femoral head; where the bearing surface and supportive bone structure of the acetabulum is normal; and where acetabular replacement is neither required nor desirable

*** WARNING: The *Durom* Femoral component is not approved for use with the *Durom* Acetabular cup for total hip surface replacement arthroplasty in the USA.**

Comparison to Predicate Device:

The femoral components of the *Durom*® Hip Resurfacing System have the same intended use,

	similar performance characteristics, are made of the same material and are similar in design to the predicate devices.
Performance Data (Non-clinical)	The results of non-clinical (laboratory) performance testing demonstrate that the device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zimmer, Inc.
% Mr. Anthony Francalancia
P.O. Box 708
Warsaw, Indiana 46581-4605

APR 26 2007

Re: K070292
Trade/Device Name: Durom® Hip Resurfacing System, femoral components
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis
Regulatory Class: II
Product Code: KXA
Dated: March 20, 2007
Received: March 21, 2007

Dear Mr. Francalancia:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K070292

Device Name:

Durom® Hip Resurfacing System, femoral components

Indications for Use:

FOR HEMI-HIP RESURFACING ARTHROPLASTY:

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (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)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K070292