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SPECIAL 510(K) DEVICE MODIFICATION
SC Ceramic Ball Heads
August 16, 2005

SEP - 6 2005

510(k) Summary of Safety and Effectiveness
[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:	Mr. Hartmut Loch Director, Regulatory Affairs & Official FDA Correspondent Orthopedic Alliance, LLC 41558 Eastman Drive, Suite A Murrieta, CA 92562 Tel: 951-304-9001 Fax: 951-304-9101
Trade name:	SC Ceramic Ball Heads
Common name:	Ceramic Ball Heads
Classification name:	Hip Joint Metal/Ceramic/Polymer Semi-Constraint Cemented or Non-Porous Uncemented Prosthesis Class II, Orthopedic Device Panel 87
Product Code:	LZO
Device Description and Characteristics:	We added 6 sizes, 28 S, 28 M, 28 L, 32 S, 32 M, and 32 L of ceramic ball heads to the SC Total Hip System, which was cleared for marketing by FDA on 10/15/03 (K031474). These ball heads allow the surgeon a further option to meet the patient's needs.
Indications:	The SC Ceramic Ball Heads are indicated for use in the treatment of severely disabled hip joints resulting from painful osteo-,rheumatoid and post-traumatic arthritis, and the late stages of avascular necrosis, and for revision of previous hip surgeries. The SC Femoral Hip Stem is indicated for use with or without bone cement. The SC Acetabular Cup is for use with bone cement only.
Performance data:	Biomechanical tests have been performed. The test results were equivalent to other similar implants and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Mr. Hartmut Loch
Director, Regulatory Affairs
Orthopedic Alliance, LLC
41558 Eastman Drive, Suite A
Murrieta, California 92562

Re: K052237
Trade/Device Name: SC Ceramic Ball Heads
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO
Dated: August 16, 2005
Received: August 18, 2005

Dear Mr. Loch:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

SPECIAL 510(K) DEVICE MODIFICATION
SC Ceramic Ball Heads
August 16, 2005

510(k) Number: **K052237**

Device Name(s): SC Ceramic Ball Heads

Indications for Use:

The SC Ceramic Ball Heads are indicated for use in the treatment of severely disabled hip joints resulting from painful osteo-,rheumatoid and post-traumatic arthritis, and the late stages of avascular necrosis, and for revision of previous hip surgeries. The SC Femoral Hip Stem is indicated for use with or without bone cement. The SC Acetabular Cup is for use with bone cement only.

Prescription Use Yes AND/OR Over-The-Counter-Use No
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K052237