K083566

510(k) Summary
Smith & Nephew R3 Constrained Liners

MAR 3 2009

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 East Brooks Road, Memphis, TN ,38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6017
CONTACT PERSON:	Nicholas B. Tabrizi
DATE SUMMARY PREPARED:	December 2, 2008
TRADE OR PROPRIETARY DEVICE NAME:	Smith & Nephew R3 Constrained Liners
COMMON OR USUAL NAME:	Constrained Liner
CLASSIFICATION NAME:	21 CFR 888.3310 - Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis
DEVICE CLASS:	Class II
PANEL CODE:	Orthopaedics/87 KWZ

A. INTENDED USE:

The R3 Constrained Liner Acetabular System is a cemented or uncemented prosthesis intended to replace a hip joint. The Constrained Liner is intended for primary or revision patients at high risk for hip dislocation due to a history of prior dislocation, bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered. The R3 Constrained Liner is intended for single use only.

B. DEVICE DESCRIPTION:

The R3 Constrained Liner and Shell Construct is a multi-piece acetabular component made up of an R3 Shell and the Constrained Liner Construct. The Constrained Liner Construct includes a bipolar bearing which articulates with a captured outer polyethylene liner, locking ring and outer poly support ring.

The R3 Constrained Liner may be used with previously implanted femoral stems, femoral heads and acetabular shells as in a revision case, or it may be used in primary cases and implanted along with a shell, head and stem. The R3 Constrained liner was designed to be used with existing Smith & Nephew hip components. The R3 Constrained Liner should not be used with ceramic femoral heads or skirted femoral heads of any material.

C. SUBSTANTIAL EQUIVALENCE INFORMATION:

The Smith & Nephew R3 Constrained Liner is similar to the following commercially available devices regarding design features, overall indications, materials, sterilization and manufacturing:

Table 14: Predicate Constrained Liner Systems

Manufacturer	Description	Submission Number	Clearance Date
Osteonics Corporation	Osteonics Constrained Acetabular Insert	P960047	6/10/1997
Smith & Nephew, Inc.	REFLECTION Constrained Liner	K021803	12/23/2002

Smith and Nephew, Inc.	Global Bipolar System	K023743	1/23/2003
Centerpulse Orthopaedics, Inc.	Epsilon Durasul Constrained Acetabular Liner	K030923	10/03/2003

D. SUMMARY OF TECHNOLOGICAL COMPARISON:

The intended use, design, and materials of the R3 Constrained Liners are substantially equivalent to the previously cleared Osteonics Constrained Liners (P960047). Design Control Activities have been completed and the results indicated that the subject device is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 2009

Smith & Nephew, Inc.
Orthopaedic Division
% Mr. Jason Sells
Manager, Regulatory Affairs
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K083566
Trade/Device Name: Smith & Nephew R3 Constrained Liners
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: December 2, 2008
Received: December 3, 2008

Dear Mr. Sells:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

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): K083566

Device Name: Smith & Nephew R3 Constrained Liner

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Prescription Use (Part 21 CFR 801 Subpart D)	X	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

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