Summary of Safety and Effectiveness
Smith & Nephew Competitor Deuce Femoral Components

Contact Person and Address
Jason Sells
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116
(901) 399-5520

Date of Summary: June 28, 2006

JUL - 6 2006

Name of Device: Competitor Deuce Femoral Components
Common Name: Knee Prosthesis

Device Description
The components are used to replace the medial condyle and patellofemoral regions of a femoral knee joint. The Competitor Deuce femoral components will initially be available in both cobalt chrome and Oxinium. The overall design of the Competitor Deuce femoral components is based upon the existing Hybrid Knee femoral components and Competitor Duo femoral components subject of K042896 and K052265, respectively.

Device Classification
21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis – Class II

Mechanical and Clinical Data
A review of the mechanical and clinical data indicated that the Competitor Deuce femoral components are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Intended Use
The Competitor Deuce femoral components are intended to be used for those patients whereby conditions exist that can not be solely addressed by a device that treats a single compartment (i.e. unicondylar or patellofemoral prosthesis) of the knee.

Indications include:

- Post-traumatic arthritis;
- Degenerative arthritis; and
- Failed osteotomies, hemiarthroplasties; and unicompartmental replacement

These indications will be used for the Competitor Deuce femoral components, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

The Competitor Deuce femoral components are single use only and are intended for implantation only with bone cement.

Substantial Equivalence Information
The Smith & Nephew Competitor Deuce femoral components are similar to the following commercially available devices regarding design features, overall indications, and materials:

- Smith & Nephew, Inc. Hybrid Knee Femoral (K042896)
- Smith & Nephew Competitor Duo Knee Femoral Component (K052265)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2006

Mr. Jason Sells
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K061569
Trade/Device Name: Competitor Deuce Femoral Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: NPJ
Dated: June 28, 2006
Received: June 29, 2006

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 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, M.S.
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): K061569

Device Name: Competitor Deuce Femoral Components

Indications for Use:

The Competitor Deuce femoral components are intended to be used for those patients whereby conditions exist that can not be solely addressed by a device that treats a single compartment (i.e. unicondylar or patellofemoral prosthesis) of the knee.

Indications include:

- Post-traumatic arthritis;
- Degenerative arthritis; and
- Failed osteotomies, hemiarthroplasties; and unicompartmental replacement

These indications will be used for the Competitor Deuce femoral components, whereby the medial condyle and patellofemoral regions have been affected by one or more of these conditions.

The Competitor Deuce femoral components are single use only and are intended for implantation only with bone cement.

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)

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

510(k) Number K061569