Smith & Nephew, Inc.
Summary of Safety and Effectiveness
TC-Plus Primary Knee System

Contact Person and Address
Rishi Sinha
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Reconstruction
1450 Brooks Road
Memphis, TN 38116
(901)399-6054

Date of Summary: 09/28/2007

NOV 2 0 2007

Name of Device: Smith & Nephew TC-Plus Primary Knee System
Common Name: TC-Plus Primary Knee System

Device Description

Subject of this premarket notification is the TC-PLUS Primary Knee System. The TC-PLUS Primary Knee System is a tricompartmental total knee prosthesis comprised of femoral, patellar, and tibial components with an ultra-high molecular weight polyethylene articular insert. The femoral and tibial baseplate components are offered with or without a plasma-sprayed titanium coating.

The TC-PLUS Primary Knee System is comprised of existing implant components of the previously-cleared VKS Knee System and the TC-PLUS Solution Knee System. The femoral components are the previously-cleared TC-PLUS Solution femoral components available with (K011258) or without (K000666) a titanium plasma-spray coating. The articular insert and tibial baseplate components in the TC-PLUS Primary Knee System are identical to those of the VKS Knee System (K022204). The titanium plasma-sprayed tibial baseplates in the system feature holes to accept cancellous bone screws[1] for supplemental fixation. The patellar components of the subject knee system are the existing patellar implants cleared as part of K000666.

There are no new implant designs included in this premarket notification other than the addition of a size 12 tibial baseplate and size 20mm thick articular inserts. This 510(k) seeks to combine two existing knee systems into one and to also harmonize the sizing for both systems.

Device Classification

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

Indications for Use

The TC-Plus Primary Knee is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision knee arthroplasy. It is indicated for degenerative, post traumatic or rheumatoid arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, in particular in the event of patello-femoral erosion, functional disability or an earlier

[1] The cancellous bone screws used with the TC-PLUS Primary Knee System are existing bone screws cleared as part of 510(k) K011719 and K994146.

patellectomy; moderate varus, valgus or flexure deformity and to correct earlier unsuccessful attempts at surgery.

Substantial Equivalence Information

The overall design of the Smith & Nephew TC-Plus Primary Knee System is substantially equivalent to previously cleared devices listed below:

Table 1: Cleared Predicate Devices

MANUFACTURER	DESCRIPTION	510(K)	CLEARANCE DATE
PLUS Orthopedics AG	TC-PLUS Solution Knee	K000666	10/13/00
PLUS Orthopedics AG	TC-PLUS Porous Femoral Components	K011258	5/24/01
PLUS Orthopedics AG	VKS Knee System	K022204	10/18/02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2007

Smith & Nephew, Inc.
% Mr. Rishi Sinha
Regulatory Affairs Specialist
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K072858
Trade/Device Name: TC-PLUS Primary Knee System
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
Dated: October 3, 2007
Received: October 5, 2007

Dear Mr. Sinha:

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). 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
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): K072858
Device Name: TC-PLUS Primary Knee System

Indications for Use:

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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

510(k) Number K072858