K033509

NOV 2 8 2003

510(k) Summary of Safety and Effectiveness
VersaBond® Bone Cement

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	November 5, 2003
Contact Person:	David Henley Senior Clinical/Regulatory Affairs Specialist Tel: (901) 399-6487 Fax: (901) 398-5146
Proprietary Name:	VersaBond® Bone Cement
Common Name:	Polymethylmethacrylate (PMMA) Bone Cement
Classification Name and Reference:	Polymethylmethacrylate (PMMA) Bone Cement 21 CFR 888.3027, Class II
Device Product Code and Panel Code:	LOD/Orthopedics/87

Device Description:

VersaBond Bone Cement consists of two separate components: polymer powder and monomer liquid. The two components are packaged together and are pre-measured, sterilized components which, when mixed, form a radiopaque, rapidly setting bone cement.

Intended Use:
VersaBond Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, osteoporosis, secondary severe joint destruction following trauma or other conditions, and revision of previous arthroplasty procedures.

Technological Characteristics:
The chemical formulation of VersaBond Bone Cement, that is the subject of this submission, is identical to that of the device cleared under K001160. Similarities include the identical chemical constituents for the bone cement / liquid monomer and identical indications for use. The device is designed to incorporate identical or very similar physical and mechanical properties.

Substantial Equivalence Information:
The indications for use, chemical formulation, and design features of VersaBond Bone Cement are substantially equivalent to the device cleared under K001160.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 28 2003

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 E. Brooks Road
Memphis, Tennessee 38116

Re: K033509
Trade/Device Name: Versabond Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: November 5, 2003
Received: November 6, 2003

Dear Mr. Henley:

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.

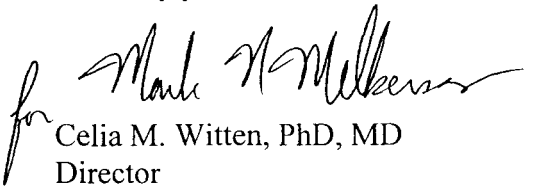
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

VersaBond® Bone Cement

510(k) Number (if known): K033509

Device Name: VersaBond® Bone Cement

Indications for Use:

VersaBond® Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee, and other joints to fix plastic and metal prosthetic parts to living bone when reconstruction is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, osteoporosis, secondary severe joint destruction following trauma or other conditions, and revision of previous arthroplasty procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milham

Division Sign-Off

Division of General, Restorative and Neurological Devices

510(k) Number K033509

Prescription Use ✓ OR Over-The Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)