510(k) Summary for Simplex™ P with Tobramycin

K014199

Proprietary Name:	Simplex™ P with Tobramycin Bone Cement
Common Name:	Antibiotic Bone Cement
Classification Name and Reference:	21 CFR 888.3027 Polymethylmethacrylate (PMMA) Bone Cement
Proposed Regulatory Class:	II
Device Product Code:	OR (87) LOD
For Information contact:	Jennifer A. Daudelin Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 (201) 831-5379 Fax: (201) 831-6038 Email: Jdaudelin@howost.com
Date Summary Prepared:	April 28, 2003

MAY 0 6 2003

Device Description

Simplex™ P with Tobramycin is an acrylic bone cement intended for the fixation of prostheses to living bone for use in second stage revision for total joint arthroplasty. The cement is packaged in two sterile components; a liquid monomer component and a powder copolymer component. The liquid monomer component is comprised of methyl methacrylate, N.N-dimethyl-p-toluidine, and hydroquinone. The powder copolymer component consists of methylmethacrylate-styrene copolymer, polymethylmethacrylate, barium sulfate U.S.P., and tobramycin sulfate U.S.P. The liquid and powder components are mixed together resulting in the exothermic polymeric formation of a soft, pliable, dough-like mass. As the reaction progresses, a cement-like complex is formed.

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Intended Use

Simplex™ P with Tobramycin is indicated for the fixation of prostheses to living bone for use in the second stage of a two-stage revision for total joint arthroplasty.

Substantial Equivalence

Simplex™ P with Tobramycin is substantially equivalent in intended use, overall materials, mechanical properties, and operational principles to Surgical Simplex® P Radiopaque Bone Cement (Howmedica Osteonics N-17-004).

Performance Data

Information on the safe use of Simplex™ P with Tobramycin was initially gathered through traditional literature searching. Information in published papers was supplemented by contacting authors of the relevant papers for additional unpublished details. Finally, arthroplasty registries were contacted to determine whether they had data that might be relevant to the safe use of this product.

The cumulative results of extensive in vitro and in vivo test data show that a balance is achieved between antibiotic release and mechanical integrity without threats of systemic toxicity or compromised mechanical function.

Additional in vivo studies were performed, which evaluated the antibiotic release from cement polymerized in situ in rabbits. Local concentrations were measured in the femoral bone bed surrounding the cement, following animal sacrifice and excision, as well as systemic levels drawn throughout the study. The values predicted by the model correlate very well with clinical data from hemovac, serum, urine, and bone samples as reported by several clinicians.

In summary, the testing demonstrates that, in terms of safety and mechanical properties, Simplex™ P with Tobramycin bone cement is substantially equivalent to the legally marketed predicate Surgical Simplex® P Bone Cement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

Ms. Jennifer A. Daudelin
Regulatory Affairs Specialist
Stryker Howmedica Osteonics
59 Route 17 South
Allendale, NJ 07401

Re: K014199
Trade/Device Name: Simplex™ P with Tobramycin
Regulation Number: 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: February 3, 2003
Received: February 4, 2003

Dear Ms. Daudelin:

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.

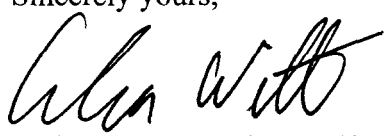
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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, Ph.D., M.D.
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): K014199

Device Name: Simplex™ P with Tobramycin

Indications for Use:

Simplex™ P with Tobramycin is indicated for the fixation of prostheses to living bone for use in the second stage of a two-stage revision for total joint arthroplasty.

for Mark N Milleren

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

510(k) Number K014199

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)