

510(k) Summary of Safety and Effectiveness
Simplex™ P SpeedSet Bone Cement with Tobramycin

FEB 26 2007

Proprietary Name: Simplex™ P SpeedSet with Tobramycin Bone Cement

Common Name: Antibiotic PMMA Bone Cement

Classification Name and Reference: Polymethylmethacrylate (PMMA) bone cement
21 CFR §888.3027

Regulatory Class: Class II

Device Product Code: 87 MBB - Polymethylmethacrylate (PMMA) bone cement.

Device Manufacturer: Howmedica International S. de R.L.
Raheen Business Park, Limerick, Ireland

For Information contact: Tiffani Rogers
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07432
Phone: (201) 831-5612
Fax: (201) 831-6038
E-Mail: Tiffani.Rogers@stryker.com

Date Summary Prepared: February 15, 2007

Device Description

Simplex P SpeedSet with Tobramycin Bone Cement is a radiopaque bone cement premixed with antibiotic capable of being applied digitally and with a syringe. The cement will be available in 10-pack or 1-pack dispensers, with each individual pack containing one powder pouch of 41.1 g unit of sterile polymeric powder and one 20.0ml ampoule of sterile monomer, for single-use. The working time of the Simplex P SpeedSet with Tobramycin Bone Cement is approximately 5.36 minutes, with a dough time of 2.56 minutes and a setting time of 9.6 minutes.

Indications For Use:

Simplex P SpeedSet with Tobramycin bone cement 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:

The Simplex P SpeedSet with Tobramycin bone cement has the same indications, same liquid monomer and similar powder component as Simplex P with Tobramycin bone cement (K014199 cleared 06 May 2003). The handling properties of Simplex P SpeedSet with Tobramycin are the same as those with Simplex P SpeedSet (K053198 cleared 26 January 2006). Howmedica Osteonics Corp. believes the Simplex P SpeedSet with Tobramycin bone cement to be substantially equivalent to Simplex P with Tobramycin and Simplex P SpeedSet bone cements.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Orthopaedics
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

FEB 26 2007

Re: K063857

Trade/Device Name: Simplex[®] P SpeedSet with Tobramycin Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: MBB
Dated: December 22, 2006
Received: December 28, 2006

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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 (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

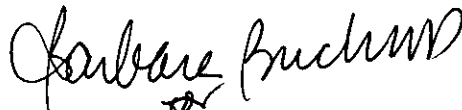
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Tiffany Rogers

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) 276-0210 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Simplex® P SpeedSet with Tobramycin Bone Cement

Indications

Simplex P SpeedSet with Tobramycin Bone Cement 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.

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use _____

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

510(k) Number K063857