NOV 2 4 2009

510 (k) Summary

510(k) Number:	**K092773**
Official correspondent:	CHRISTINE L. BRAUER, PH.D. US AGENT
Manufacturer/Submitter:	TECRES S.P.A. VIA ANDREA DORIA 37066 SOMMACAMPAGNA VERONA - ITALY FDA OWNER/OPERATOR ID #: 9033624
Date:	NOVEMBER 23, 2009
Trade/Proprietary model names:	CEMEX GENTA CEMEX GENTA SYSTEM CEMEX SYSTEM GENTA FAST
Common name:	BONE CEMENT
Device classification name:	POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT
Regulation number:	888.3027
Device class:	II
Classification panel:	ORTHOPAEDIC
Classification product code:	LOD

DEVICE DESCRIPTION:

All Cemex Genta bone cements contain the same individual chemical constituents.
The liquid components contain methylmethacrylate, N-N dimethyl p-toluidine and hydroquinone.
The dry powder component contains polymethylmethacrylate, barium sulphate, benzoyl peroxide and gentamicin sulphate.

INTENDED USE:

Cemex Genta/Cemex Genta System/Cemex Genta System Fast bone cement is indicated for the fixation of prostheses to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

PREDICATE DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED:

The modified Cemex Genta, Cemex Genta System and Cemex Genta System Fast bone cements are substantially equivalent to the following predicate devices:

- Cemex Genta and Cemex Genta System cleared via K033596
- Cemex Genta System Fast cleared via K043403

SUBSTANTIAL EQUIVALENCE:

Performance testing was conducted to verify that the modified bone cement performance continue to be adequate for in vivo applications and meet the requirements of ISO5833 and ASTM 451-99.

Chemical-physical and mechanical properties, gentamicin release and stability data were evaluated and found to support the substantial equivalence of the device.

Based on the same fundamental scientific technology and on results of the verification activities, it is concluded that the Cemex Genta bone cements manufactured with gentamicin sulphate are substantially equivalent to the legally marketed ones.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Tecres S.p.A.
% Brauer Device Consultants, LLC
Christine L. Brauer, Ph.D.
Regulatory Affairs Consultant
7 Trailhouse Court
Rockville, Maryland 20850

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Re: K092773
Trade/Device Name: Cemex Genta/Cemex Genta System/Cemex Genta System Fast
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: October 27, 2009
Received: October 28, 2009

Dear Dr. Brauer:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number (if known): K092773

Device Name: Cemex Genta/Cemex Genta System/Cemex Genta System Fast

Indications for Use: Cemex Genta/Cemex Genta System/Cemex Genta System Fast bone cement is indicated for the fixation of prostheses to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Prescription Use __x_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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