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Exactech®

MAY 1 0 2004

2320 NW 66TH COURT
GAINESVILLE, FL 32653
352-377-1140
FAX 352-378-2617

Tecres

Cemex® Genta bone cement

Traditional 510(k)#K033596

Summary of Safety and Effectiveness

Applicant/Consultant:

Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

Phone: (352) - 377 - 1140
Fax: (352) - 378 - 2617

FDA Establishment # 1038671

Manufacturer:

TECRES S.p.A
Via Andrea Doria 10,
37066 Sommacampagna, Verona, Italia

FDA Owner number: # 9033624

Contact:

Gary J. Miller, PH.D.
Exec. Vice President of Research & Development
Exactech, Inc.

Date:

May 5, 2004

Tecres
Cemex® Genta bone cement
Traditional 510(k)#K033596

Summary of Safety and Effectiveness

Trade Names: Cemex Genta Bone Cement
Cemex Genta System Bone Cement

Common Name: Bone Cement

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement

Legally Marketed Device for Substantial Equivalence Comparison:

Model	Manufacturer	510(k) Number
Cemex System	Tecres, S.p.A.	#K000943

INDICATIONS FOR USE
Cemex Genta / Cemex Genta System 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.

CONTRAINDICATIONS
Cemex Genta / Cemex Genta System bone cement **is contraindicated in primary orthopaedic musculoskeletal surgical procedures.**

Cemex Genta / Cemex Genta System bone cement is contraindicated in patients who are allergic or sensitive to any of its components, including Gentamicin Sulphate.

If the patient has a history of hypersensitivity or serious toxic reactions to aminoglycosides, the use of any other aminoglycosides may also be contraindicated due to the known cross-sensitivity of patients to drugs in this class.

CEMEX GENTA bone cement is contraindicated in the presence of active or incompletely treated infection, at the site where the bone cement is to be applied.

Cemex Genta / Cemex Genta System bone cement is contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.

Cemex Genta / Cemex Genta System bone cement must be considered carefully in the presence of myastenia gravis.

There may be increased risk of ototoxicity from gentamicin, if other ototoxic drugs such as cisplatin (an antineoplatic agent) and vancomycin (another antibiotic) are given at the same time. There also appears to be a synergistic effect of loop diuretics, such as furosemide or ethacrynic acid, and also loud noise, when combined with gentamicin.

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GENERAL DESCRIPTION – Substantial Equivalency Information

Cemex Genta System and Cemex Genta bone cement are substantially equivalent to the predicate Cemex System bone cement (#K000943). The physical and chemical characteristics of the individual components are identical to those of Cemex System, apart from the additional presence of gentamicin sulphate in the powder.

The liquid component contains methylmethacrylate, N-N dimethyl p-toluidine, and hydroquinone. The dry powder component contains polymethylmethacrylate, barium sulphate, benzoyl peroxide and gentamicin sulphate.

Performance testing shows that the proposed devices are equivalent to the predicate and meet the requirements of ISO 5833 and ASTM 451-99.

PACKAGING

The packaging design for ***Cemex Genta System*** bone cement is identical to Cemex System bone cement (#K000943) except for the addition of an aluminum bag that serves as a moisture barrier. The packaging design for ***Cemex Genta*** bone cement is identical to Cemex RX, ISOPLASTIC and XL bone cements (#K021715) except for the addition of an aluminum bag that serves as a moisture barrier.

STERILITY ASSURANCE

The powdered component is sterilized by ethylene oxide (EO) to a Sterility Assurance Level (SAL) of 10^{-6}. The liquid component is sterilized by a membrane filtration technique to a SAL of 10^{-3}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2004

Ms. Lisa Simpson
Senior Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K033596
Trade/Device Name: Cemex Genta / Cemex Genta System Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD and MBB
Dated: February 24, 2004
Received: February 25, 2004

Dear Ms. Simpson:

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) 594-4639. 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 may be obtained 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,

for Mark N Milhous

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

Tecres
Cemex® Genta Bone Cement
Indications for Use

510(k) Number: **#K033596**

Device Names: **Cemex Genta / Cemex Genta System Bone Cement**

INDICATIONS FOR USE

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Prescription Use ___X___ or Over the Counter Use ___No___

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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