K031430

Exactech, Inc.
Tecres Cemex® System Fast
Bone Cement

MAY 22 2003

Special 510(k)
Summary of Safety and Effectiveness

Trade Names: Cemex System Fast

Common Name: Bone Cement

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement

Legally Marketed Devices for Substantial Equivalence Comparison:

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

Device Description:

INTENDED USE

CEMEX SYSTEM bone cement is intended to be used for the fixation of plastic and metal joint prostheses to host bone.

INDICATIONS FOR USE

CEMEX SYSTEM bone cement is indicated for the fixation of prostheses to bone in orthopaedic musculoskeletal procedures for osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, tramatic arthritis, congenital deformities, avascular necrosis, post-traumatic degenerative problems of the joint, sickle cell anemia, osteoporosis, collagen disease and for the revision of previous arthroplasty procedures.

CONTRAINDICATIONS

CEMEX SYSTEM bone cement is contraindicated in the presence of active or incompletely treated infection which could involve the site where the cement is to be applied.

CEMEX SYSTEM bone cement is contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.

CEMEX SYSTEM bone cement is contraindicated in patients who are allergic to any of its components.

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GENERAL DESCRIPTION – Substantial Equivalency Information

The individual chemical constituents in Cemex System Fast bone cement are identical to those in the predicate Cemex System cement (#K000943). The liquid component contains methylmethacrylate, N-N dimethyl p-toluidine, and hydroquinone. The dry powder component contains polymethylmethacrylate, barium sulphate and benzoyl peroxide. The only difference is that the predicate Cemex System has a 2.7:1 powder-to-liquid ratio compared to the 2.4:1 ratio the new Cemex System Fast product. The powder-to-liquid ratio reduction results in a quicker setting time to accommodate various application techniques.

PACKAGING

The Cemex System Fast has identical packaging as the predicate CEMEX System. The product is contained in a double blister pack sealed with Tyvek® lids. The outer packaging is a heavy weight cardboard box.

MIXING & APPLICATION

Use of Cemex System Fast bone cement takes place in two consecutive stages. During the first stage, the glass ampoule containing the liquid monomer is broken to allow the component to flow into the chamber containing the powdered constituents. The device is then used as a closed manual mixing device. Mixing is accomplished by firmly striking the device against the palm of the hand and rotating at each strike. Because no direct contact is made between the components and the user, volitile release into the local environment and possibility of contamination is minimized. In the second stage, the container is attached to an application gun device and used as a syringe while the cement is still in a semi-fluid state. The transparency of the mixing device provides for preliminary inspection of the suitability of the cement components and the visualization of the mixing and application stages as required by ISO 5833. Detailed instructions for use and precaution/warning information is outlined in the instruction leaflet provided with the product.

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 22 2003

Ms. Lisa Simpson
Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, FL32653

Re: K031430
Trade Name: Tecres Cemex System Fast Bone Cement
Regulation Number: 21 CRF 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: May 5, 2003
Received: May 6, 2003

Dear Ms. Simpson:

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 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.

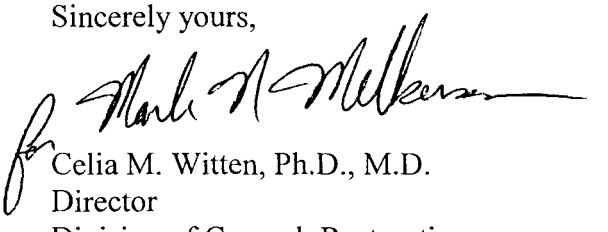
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,



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 System Fast Bone Cement

Indications for Use

510(k) Number: K031430

Device Names: Cemex System Fast Bone Cement

INTENDED USE

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INDICATIONS FOR USE

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for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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

510(k) Number K031430

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____