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K021715

Exactech, Inc.
Tecres Cemex® System
Bone Cement

Special 510(k)
Summary of Safety and Effectiveness

Trade Names: Cemex ISOPLASTIC Bone Cement
Cemex RX Bone Cement
Cemex XL Bone Cement

Common Name: Bone Cement

Classification Name: Polymethylmethacrylate (PMMA)
Bone Cement

Legally Marketed Devices for Substantial Equivalence Comparison:

Model	Manufacturer
Cemex System	Tecres, S.p.A. (#K000943)
CMW3	CMW Laboratories (Distributed by Dow Corning Wright)
Simplex P	Howmedica
Palacos R	Merck (Distributed by Smith & Nephew)
Dough-Type	Zimmer

Device Description:

INTENDED USE
CEMEX RX, CEMEX ISOPLASTIC and CEMEX XL bone cements are intended to be used for the fixation of plastic and metal joint prostheses to host bone.

INDICATIONS FOR USE

CEMEX 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.

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CONTRAINDICATIONS

CEMEX 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 bone cement is contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.
CEMEX bone cement is contraindicated in patients who are allergic to any of its components.

GENERAL DESCRIPTION – Substantial Equivalency Information

The chemical constituents in CEMEX RX, ISOPLASTIC, and XL bone cements 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. Like the predicate CEMEX SYSTEM Bone Cement (#K000943), the ratio between the powder and liquid components of the proposed cements is 3:1.

The proportion of each ingredient in the ISOPLASTIC and RX models varies slightly from the predicate model. The XL bone cement formulation is identical to that of CEMEX SYSTEM (#K000943). The differences result in a range of viscosities to accommodate various application techniques.

Cemex XL, RX and ISO bone cements are also similar to other competitive cement products including "Simplex P" by Howmedica, "CMW 3" by Dow Corning Wright, "Dough" by Zimmer, and "Palacos R" by Smith & Nephew. Several of the predicate devices are indicated for the fixation of pathological fractures but Cemex bone cements are not indicated for this application.

PACKAGING

The liquid monomer component is contained in a trumpet shaped amber glass vial. The powder component is contained in a paper polyethylene (PE) film sachet. The product is packaged in unitary blister pack with Tyvek® lids. The outer packaging is a heavy weight cardboard box.

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

JUN 12 2002

Ms. Lisa Simpson
Regulatory Representative
Exactech®
2320 NW 66th Court
Gainesville, Fl 32653

Re: K021715
Trade Name: Tecres Bone Cement RX, ISOPLASTIC, XL
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: May 22, 2002
Received: May 23, 2002

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. Additionally, for questions on the promotion and advertising of your device, 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). 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 Melkerson

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 Bone Cement

Indications for Use

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510(k) Number: K021715

Device Names: Cemex ***Rx*** Bone Cement
Cemex ***XL*** Bone Cement
Cemex ***Isoplastic*** Bone Cement

INTENDED USE

CEMEX bone cement is intended to be used for the fixation of artificial joint prostheses to the host bone.

INDICATIONS FOR USE

CEMEX bone cement is indicated for the fixation of protheses 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 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.
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Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over the Counter Use _____

for Mark A Millenson

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

510(k) Number K021715