K040755

JUN 17 2004

Special 510(k) Summary of Safety and Effectiveness

This 510(k) Summary for Exactech Resorbable Room Temperature Bone Paste is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

1. Submitter:

Exactech Inc.
2320 NW 66th Court
Gainesville, Florida 32653
Telephone 352-377-1140
Fax 352-378-2617

Contact person:

Steve Lin, D.Sc
Vice President, Advanced Technology & Business Development
Exactech Inc.
Telephone 352-377-1140
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Date of original submission: 03-19-2004

FDA Establishment Number 1038671

2. Proprietary Name: Exactech Resorbable Room Temperature Bone Paste

Common Name: Bone void filler

Product Code: MQV, MBP

Device Class: Class II

Classification Panel: Orthopaedic

3. Legally Marketed Devices for Substantial Equivalence Comparison:

Product Code	Manufacturer	510(k) Number	Product
MQV, MBP	Exactech Inc.	K020078	Exactech Resorbable Bone Paste

4. Comparison to the Predicate Device(s):

Exactech Resorbable Room Temperature Bone Paste shares the same components, function and intended use as the predicate device, Exactech Resorbable Bone Paste. Modifications to this device do not affect safety and efficacy of the device and is therefore substantially equivalent to predicate device.

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5. Device Description:

Exactech Resorbable Room Temperature Bone Paste is a mixture of demineralized bone matrix (DBM) in a bioinert and bioabsorbable polyethylene glycol (PEG) based polymer and is provided as an aseptic manufacture single use, ready to use implantable device derived from a single donor. Exactech Resorbable Room Temperature Bone Paste gradually resorbs and is replaced with new bone during the healing process.

6. Indications for Use

Exactech Resorbable Room Temperature Bone Paste is intended for use as a bone graft extender (extremities, spine, pelvis) and as a bone void filler for bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Exactech Resorbable Room Temperature Bone Paste may be used with rigid fixation systems.

7. Contraindications:

Exactech Resorbable Room Temperature Bone Paste is not intended to provide structural support during the healing process; therefore, Exactech Resorbable Room Temperature Bone Paste is contraindicated in cases where structural support of the skeletal system is required by the graft during healing.

This allograft should not be implanted into sites with an active infection.

Polymixin Sulfate B and Bacytracin are used in processing this graft and trace amounts remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity.

8. Safety and Effectiveness Information:

Exactech Resorbable Room Temperature Bone Paste is aseptically manufactured for single patient use. Each lot of Exactech Resorbable Room Temperature Bone Paste undergoes microbiologic testing for sterility in conformance with 21CFR610.12.

Human demineralized bone used in Exactech Resorbable Room Temperature Bone Paste is known to be biocompatible based on its long history of use without adverse reactions or complications.

The polymer carrier used in Exactech Resorbable Room Temperature Bone Paste was demonstrated to be biocompatible in accordance with ISO 10993 biocompatibility testing and other in vivo testing.

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a. Osteoinductive Potential

Test samples from each lot of Exactech Resorbable Room Temperature Bone Paste are implanted bilaterally into the gastrocnemius muscle of 2 athymic nude mice in accordance with the ASTM Draft Standard *Guide for the Assessment of Bone Inductive Material.* A minimum of two implanted samples must demonstrate osteoinductive potential as assessed by histological evidence of endochondral bone formation, including the presence of cartilage or chondrocytes, active osteoblasts, osteoid, newly formed and mineralized bone and/or marrow and associated fat cells. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

b. Viral Inactivation Validation

A viral reduction study was conducted by a CLIA certified testing laboratory using four virus models representing RNA, DNA, envelope and non-envelope virus, which included: 1) *Hepatitis A Virus (HAV)*, non-enveloped, RNA-containing picornavirus 2) *Human immunodeficiency virus type 1* (HIV-1) enveloped, RNA-containing retrovirus, 3) *Porcine parvovirus (PPV)* non-enveloped, DNA-containing parvovirus, which serves as a model for other parvovirus such as human parvovirus B19 and 4) *Pseudorabies virus (PrV)*, enveloped, DNA-containing virus belonging to the Herpesviridae family and serves as a model for other herpesviruses such as Cytomegalovirus (CMV). This study demonstrates the demineralization process used on donor bone contained in Exactech Resorbable Room Temperature Bone Paste significantly diminishes these model viruses and can reasonably be anticipated to diminish the titers of other viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Ms. Rebecca S. Roberts CTBS
Regulatory Affairs Representative - Biologics
Exactech Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K040755
Exactech Resorbable Room Temperature Bone Paste
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: May 17, 2004
Received: May 19, 2004

Dear Ms. Roberts:

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) 594-4659. 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 (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

Exactech Resorbable Room Temperature Bone Paste

Indications for Use

510(k) Number (if known): K040755

Device Name: Exactech Resorbable Room Temperature Bone Paste

Indications for Use:

Exactech Resorbable Bone Paste is intended for use as a bone graft extender (extremities, spine, pelvis) and as a bone void filler for bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Exactech Resorbable Bone Paste may be used with rigid fixation systems.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

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

510(k) Number K040755