K070794

MEDICAL BIOMAT, INC.
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JUL 10 2007

Section 5

510(k) Summary for ATLANTIK™ Bone Void Filler

OWNER:

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CONTACT:

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SUMMARY PREPARATION DATE: May 23, 2007

DEVICE:

- **PROPRIETARY NAME:** ATLANTIK™
- **USUAL NAME:** Bone Void Filler
- **CLASSIFICATION NAME:** Resorbable calcium salt bone void filler device (21 CFR 888.3045)
- **DEVICE PANEL:** Orthopedic
- **PRODUCT CODE:** MQV

PREDICATE DEVICES:

➢	Biomatlante	MBCP™	Bone Void Filler	(K051774)
➢	IsoTis NV	OsSatura™ BCP	Bone Void Filler	(K030131)

DEVICES DESCRIPTION:

ATLANTIK™ is a synthetic and osteoconductive bone void filler. It is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 70% hydroxyapatite (HA) and 30% beta-tricalcium phosphate (TCP). Its porosity is interconnected and opened with a total volume ratio of 70%.

ATLANTIK™ is available in the form of irregular-shaped vial-packed granules of different sizes and blocks with various shapes and sizes.
ATLANTIK™ is provided sterile for single use.

INTENDED USE:

ATLANTIK™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. 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.
ATLANTIK™ is a bone void filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.

SUBSTANTIAL EQUIVALENCE INFORMATION:

ATLANTIK™ and the predicate devices are similar in design, materials, chemical composition and function. ATLANTIK™ and the predicate devices are made of hydroxyapatite and beta-tricalcium phosphate with similar weight ratios. They have similar porous structures in terms of porosity volume ratio, porosity size distribution and interconnectivity. ATLANTIK™ and the predicate devices are osteoconductive and have similar dissolution rates. ATLANTIK™ and the predicate devices are provided sterile and non-pyrogenic for single patient use.

TESTING:

Extensive bench testing comparing ATLANTIK™ and the predicate devices have been performed to support substantial equivalence. Phase composition has been investigated by X-ray diffraction (XRD). Chemical composition was investigated by induced coupled plasma spectrometry (ICP). Porosity was investigated by mercury intrusion porosimetry, scanning electron microscopy (SEM) and density measurements. Dissolution rate and pH of ATLANTIK™ and the predicate devices were compared in a buffered solution at pH 7.3.

CONCLUSION:

Hydroxyapatite and beta-tricalcium phosphate have been used in clinical practice for more than 25 years with no remarkable safety issues. The devices to which ATLANTIK™ claims substantial equivalence have been used safely for many years in clinical environment. Testing results demonstrate that ATLANTIK™ is as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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JUL 10 2007

Re: K070794
Trade Name: ATLANTIK™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void device
Regulatory Class: Class II
Product Code: MQV
Dated: June 12, 2007
Received: June 14, 2007

Dear Dr. Bignon,

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 (240) 276-0120). 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Aurelien Bignon, Ph.D.

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices and Radiological Devices	240-276-0120

Section 4
Indications for use

510(k) Number (if known): K070794

Device Name: ATLANTIK™

Indications for use:
ATLANTIK™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. 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.
ATLANTIK™ is a bone void filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.

Prescription Use: YES **AND/OR** **Over-The-Counter Use:** NO
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division ...
and N...

510(k) Number K070794