K070897

XI. **510 (k) SUMMARY**

SEP 17 2007

Submitter: Mr. T. H. Kim, BioQM Manager, Meta Biomed Co., Ltd., Cheongwongun, Chungbuk, Korea. Tel: 82-43-218-1983.

I. Classification Names and Numbers: Resorbable Calcium Salt Bone Void Filler Device, 21 CFR 888.3045, product code MQV.

II. Common/Usual Name: Bone void filler, bone filler, bone graft material

III. Proprietary Names: BoneMedik, and BoneMedik-S

IV. Establishment Registration Number: 9681254

V. Performance Standard: None established under section 514. However, the material meets ISO 10993 for biocompatibility, ISO 11137 Sterilization of health care products, and ISO 13409 for Sterilization validation and ISO 13779-1:2000, Implants for Surgery. Hydroxyapatite, Ceramic Hydroxyapatite.

VI. Device Description: BoneMedik and BoneMedik-S are coralline hydroxyapatite bone void fillers. They are similar except that BoneMedik-S contains about one percent silicon. Both are osteoconductive porous implant materials similar in structure to human cancellous bone. The material is trabecular hydroxyapatite. Once implanted the porous hydroxyapatite is resorbed and the reticulated spaces in the implant are infiltrated with tissue. Bone formation occurs in apposition to the BoneMedik and BoneMedik-S surface and within the interstices of the implant skeleton. As the implant resorbs, bone and soft tissue growing into the space previously occupied by the implant.

VII. Special Controls Guidance Document: Applicable sections of the guidance document, "Resorbable Calcium Salt Bone Void Filler Device, Guidance for Industry and FDA were used to design the studies described in this document. The studies used to provide the data required in the guidance document included: A. Performance Testing, Bench: Extraction material test, heavy metal contents, Ca/P ratio, shape, size, packaging and compressive strength; B. Animal Testing: Implantation tests including macroscopic and microscopic observations of bony ingrowth including x-ray photos and x-ray diffraction patterns. (C) Biocompatibility: The biocompatibility of BoneMedic and BoneMedic-S were studied in accordance with ISO 10993, cytotoxicity, sensitization and irritation, and acute stystemic toxicity. (D) Sterility:BoneMedik and BoneMedik-S are sterilized with gamma radiation. The sterilization cycles were validated to provide a minimum sterilility assurance level of 10^{-6}.

VIII. Labels and Labeling: Draft labels of BioMedik and BioMedik-S and instructions for use are provided.

IX. Indications for Use: BoneMedik and BoneMedik-S are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products provide a bone graft substitute that resorbs and is replaced with bone during the healing process.

X. Substantial Equivalence: BoneMedik and BoneMedik-S are substantially equivalent to the device classified in 21 CFR 888.3045, "Resorbable calcium salt bone void filler device," product code MQV. They are also substantially equivalent to several devices currently on the market cleared by the 510(k) process. They are substantially equivalent (and nearly identical) to the Interpore, Intl. product, "Pro Osteon Implant 500 products originally cleared under the Premarket Approval system as P860005 and after reclassification cleared under 510(k)s K990131, K980817 and others. Like Pro Osteon 500, BoneMedik and BoneMedik-S are based on natural product that provides the unique structure. BoneMedik and BoneMedik-S are also substantially equivalent to the Kensey-Nash Bone Void Filler, cleared by the Kensey Nash Corp. in K060917 and K033679, and several others.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to fill bony voids and gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or those created from traumatic injury to the bone.

2. The technological characteristics for this product are similar to those of the predicate devices and those currently on the market and have the same starting material as the closest predicate.. In addition, the technological differences are well understood in the dental industry.

3. Descriptive information provided shows that the materials from which these devices are made are well known to industry and government professionals and similar to those classified and currently used in marketed devices.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix VIII.

[End of Summary]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Meta Biomed Co., Ltd
% Mr. Tae-Hoon Kim
414-12 Mo Choong Dong
Chong Ju City
Choong Chong Buk Do,
Republic of Korea.

SEP 17 2007

Re: K070897
Trade/Device Name: BoneMedik and BoneMedik-S
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 14, 2007
Received: August 20, 2007

Dear Mr. Tae-Hoon Kim:

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,

for

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

Enclosure

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

IX. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: BoneMedik and BoneMedik-S

Indications for use:

BoneMedik and BoneMedik-S are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products provide a bone graft substitute that resorbs and is replaced with bone during the healing process.

Prescription Use__X___ (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use____ (Per 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 of General, Restorative, and Neurological Devices

510(k) Number K070897