K070012

Kyungwon Medical Suite 601 World Meridian Venture Center, 60-24 Gasan-dong, Geumcheon-gu, Seoul, Korea 153-801

510(k) Summary

Date: _____

1. Company making the submission:

DEC 27 2007

	Submitter
Name	Kyungwon Medical Co., Ltd.
Address	Suite 601 World Meridian Venture Center, 60-24 Gasan-dong, Geumcheon-gu, Seoul, Korea 153-801
Phone	+82 2 2113-8693~8
Fax	+82 2 2113-8699
Contact	Ph.D. Hwang, In Soo
Internet	http:// www.kyungwonmedinet.co.kr

2. Device :
   Trade Name – PolyBone
   Common Name – Artificial bone substitute
   Classification Name – Methyl methacrylate for cranioplasty

3. Predicate Device: BoneSource® HAC Rapid Setting Cement, Methyl methacrylate for cranioplasty, Stryker Instruments, K043334.

4. Description :
   PolyBone consists of beta-tricalcium phosphate, monocalcium monobasic, calcium sulfate hemihydrate and polyphosphate. PolyBone is indicated for use as cranioplasty cement.

5. Indication for use :
   PolyBone is a self-setting, calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

6. Review :
   Polybone has the similar technological characteristics to the predicate device; components, indication for use, chemical and performance properties.

   Components Similarities
   Both products are supplied with Powder and Liquid.

   Indication for Use Similarities

Kyungwon Medical Suite 601 World Meridian Venture Center, 60-24 Gasan-dong, Geumcheon-gu, Seoul, Korea 153-801

Both products have the same indication for use.

Chemical Similarities
Both products are made up from Calcium phosphate family.

Performance Properties Similarities
The properties of both devices have the equivalence in the doughing time, setting time, working time and pH. The different points are compressive strength and dissolution rate. The compressive strength force of predicate is 60 MPa and of Polybone is 22.7MPa. The predicate device is used in the cortical bone and Polybone is in cancellous bone. Minimum 2.6 MPa is the acceptance criteria for Type 2 in ISO 7490:2000 Dental gypsum-bonded casting investments. In the dissolution rate Polybone has more rapid rate than the predicate.

Biocompatibility
The biocompatibility of Polybone has been performed by ISO 10993-1:2003; cytotoxicity, sensitization, irritation, intracutaneous reactivity, systemic toxicity, subchronic toxicity, genotoxicity and implantation. The testing results show Polybone to be biologically safe.

Therefore, we believe that Polybone is substantially equivalent to predicated device according to the above information in terms of component, indication for use, chemical and performance priorities.

7. Conclusions :

Based on the information provided in this premarket notification Kyungwon Medical Co., Ltd. concludes that PolyBone is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2007

Kodent, Inc.
% Steve Chang, Ph.D.
President
13340E Firestone Boulevard Suite J
Santa Fe Springs, CA 90670

Re: K070012
Trade/Device Name: PolyBone®
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: November 6, 2007
Received: November 13, 2007

Dear Dr. Chang:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Indications for Use

510(k) Number (if known) K070012

Device Name: PolyBone

Indications for Use:

PolyBone is a self-setting, calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21CFR801 Subpart D) (21CFR801 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 K070012