



K 063422

510(k) SUMMARY

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92

SUBMITTER: Innovative BioCeramix Inc.
3650 Wesbrook Mall
Vancouver, BC V6S 2L2 Canada
Tel: 604-221-6800
Fax: 604-677-6129

NOV 21 2006

CONTACT: Dr. Quanzu Yang

SUMMARY PREPARED: Jul 25, 2006

TRADE NAME: BioAggregate

COMMON NAME: Root Canal Repair Filling Material

CLASSIFICATION NAME: Root Canal Filling Resin (21 CFR 872.3820, Product Code: KIF)

PREDICATE DEVICE: Dentsply International WHITE MTA MATERIAL (K011009)

For specific chemical compositions:

- Biomet, Inc. Tantalum Beads – Radiographic Marker (K010348)
- Synthes (USA) chronOSTM(K041350)
- NovaBone Products, LLC PerioGlas – Bioglass Bone Graft Particulate (K040278)

DEVICE DESCRIPTION: BioAggregate is a white hydraulic cement-like powder composed of biocompatible ceramic particles. The BioAggregate Powder promotes cementogenesis upon mixing with BioA Liquid and forms a hermetic seal inside the root canal.

- INTENDED USE:**
- Repair of Root Perforations
 - Repair of Root Resorption
 - Root End Filling
 - Apexification
 - Pulp capping

TECHNOLOGICAL CHARACTERISTICS: BioAggregate is equivalent to WHITE MTA MATERIAL, in terms of the physical state (powder-liquid mix), working time, setting time, solubility and radiopacity. Similar major chemical compounds are utilized in the production of both BioAggregate and WHITE MTA MATERIAL. Both materials are non-mutagenic and non-cytotoxic, and are designated for the same indications for use. The primary difference between



the two materials is that BioAggregate has an aluminum-free composition, which contains chemical compounds that improve BioAggregate's properties in terms of safety and effectiveness, and includes calcium phosphate.

The additional predicate devices include: Tantalum Beads – Radiographic Marker, Synthes (USA) chronOST™ and PerioGlas – Bioglass Bone Graft Particulate each containing specific chemical compounds that are equivalent to BioAggregate, providing evidence that these chemical compounds are safe and effective for medical devices use.

**NON-CLINICAL TESTS
PERFORMED:**

BioAggregate has undergone extensive bench and biocompatibility testing to provide evidences that BioAggregate's physico-chemical properties are substantially equivalent to WHITE MTA MATERIAL. Bench tests included Working Time, Setting Time, Solubility and Radiopacity. Biocompatibility tests results determined that BioAggregate is non-mutagenic, non-cytotoxic, does not cause allergenic potential to tissues after multiple uses and has good tolerance by subcutaneous tissues.

CONCLUSIONS:

BioAggregate has the same indications for use, includes similar materials and comparable technological characteristics as WHITE MTA MATERIAL. In addition, the bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. The chemical compounds of BioAggregate that were not equivalent to MTA were found to be safe and effective in Tantalum Beads – Radiographic Marker, Synthes (USA) chronOST™ and PerioGlas – Bioglass Bone Graft Particulate. Therefore, it is concluded that BioAggregate is safe, effective and substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 21 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Innovative Bioceramix Incorporated
C/O Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K063422
Trade/Device Name: BioAggregate
Regulation Number: 21 CFR 872.3820
Regulation Name:
Regulatory Class: II
Product Code: KIF
Dated: November 10, 2006
Received: November 13, 2006

Dear Mr. Devine:

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.

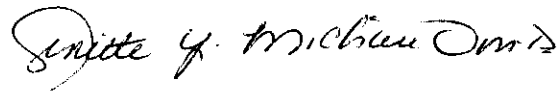
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if Known): K063422

Device Name: BioAggregate

Indications for Use:

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(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)

Susan Pump

Special Agent in Charge
Division of Anesthesiology, General Hospital,
Division Control, Dental Devices

Number: K063422