K092715

SEP 29 2009

INNOVATIVE BIOCERAMIX INC.
1628 West 75th Avenue
Vancouver, BC
V6P 6G2 Canada
Tel: 604-221-6800
Fax: 604-677-6129

510(k) SUMMARY

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

SUBMITTER: Innovative BioCeramix Inc.
1628 West 75th Avenue
Vancouver, BC
V6P 6G2 Canada
Tel: 604-221-6800 Fax: 604-677-6129

CONTACT: Quanzu Yang

SUMMARY PREPARED: August 21, 2009

TRADE NAME: iRoot BP Plus

COMMON NAME: Root Repair Material

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

PREDICATE DEVICES:

- iRoot BP (K082943)
- BioAggregate (K063422)
- Cavit-W (K875133)
- VitalCare I.V. Adminstration Set (K050906)

DEVICE DESCRIPTION: iRoot BP Plus Root Repair Material (iRoot BP Plus) is a convenient ready-to-use white hydraulic premixed bioceramic paste developed for permanent root canal repair and surgical applications. iRoot BP Plus is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot BP does not shrink during setting and demonstrates excellent physical properties. iRoot BP Plus is packaged in a preloaded container.

INTENDED USE:

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

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TECHNOLOGICAL CHARACTERISTICS:

iRoot BP Plus and iRoot BP are designated for the equivalent dental applications, and have comparable chemical and physical properties, and performance specifications. iRoot BP Plus is a modification of iRoot BP. The packaging for iRoot BP Plus includes jars and unit dose cups.

Additional predicate devices include: BioAggregate, Cavit-W and VitalCare I.V. Administration Set, each contains specific material components that are equivalent to those found in the packaging for iRoot BP Plus; providing evidence that these materials are safe and effective for medical device use. Furthermore, iRoot BP Plus and Cavit-W have similar delivery systems.

NON-CLINICAL TESTS PERFORMED:

iRoot BP Plus has undergone bench and shelf life testing, which provides evidence that iRoot BP's chemical and physical properties are substantially equivalent to iRoot BP.

CONCLUSIONS:

iRoot BP Plus has the equivalent indications for use, comparable chemical composition, physical properties and performance specifications to iRoot BP. The additional material components found in iRoot BP Plus's packaging were found to be safe and effective in BioAggregate, Cavit-W and VitalCare I.V. Administration Set. In addition, iRoot BP Plus has a comparable delivery system to Cavit-W. Therefore, it is concluded that iRoot BP Plus is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 29 2009

Mr. Quanzu Yang
President/Chief Executive Officer
Innovative BioCeramix Incorporated
1628 West 75th Avenue
Vancuver, BC V6P 6G2
CANADA

Re: K092715
Trade/Device Name: iRoot BP Plus Root Repair Material
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: August 21, 2009
Received: September 3, 2009

Dear Mr. Yang:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for

Susan Runner, D.D.S., M.A.
Acting 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): K092715

Device Name: iRoot BP Plus Root Repair Material

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)

Kai Mudy for MSK
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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