K102867

INNOVATIVE BIOCERAMIX INC.
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V6P 6G2 Canada
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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
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V6P 6G2 Canada
Tel: 604-221-6800 Fax: 604-677-6129

DEC - 3 2010

CONTACT: Quanzu Yang

SUMMARY PREPARED: October 27, 2010

TRADE NAME: iRoot FS

COMMON NAME: Fast Set Root Repair Material

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

PREDICATE DEVICES:

- iRoot BP (K082943)
- iRoot BP Plus (K092715)
- iRoot SP (K080917)
- D-PBS, Products No. D5652 (K851606)

DEVICE DESCRIPTION: iRoot FS Fast Set Root Repair Material (iRoot FS) is a convenient ready-to-use fast setting white hydraulic premixed bioceramic paste developed for permanent root canal repair of root perforation and root resorption, and root end filling, apexification and pulp capping applications. iRoot FS 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 FS does not shrink during setting and demonstrates excellent physical properties. iRoot FS is available as a preloaded syringe with disposable tips and 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 FS is a modification of iRoot BP. iRoot FS and iRoot BP are designated for the equivalent dental applications, and have comparable chemical and physical properties, and performance specifications. The packaging for iRoot FS includes syringes, jars and unit dose cups.

Additional predicate devices include: iRoot SP and D-PBS each contains specific chemical components that are equivalent to those found in iRoot FS; providing evidence that these materials are safe and effective for medical device use. Furthermore, iRoot FS and iRoot BP Plus have equivalent packaging containers and delivery systems.

NON-CLINICAL TESTS PERFORMED:

iRoot FS has undergone shelf life, bench and biocompatibility testing to provide evidence that iRoot FS's chemical and physical properties are substantially equivalent to iRoot BP. Both iRoot FS and iRoot BP have comparable flowability, working times, setting times, dimensional change following setting, solubility, shelf life and biocompatibility properties.

Biocompatibility test results determined that iRoot FS is non-cytotoxic. Since iRoot FS's chemical composition is based on the principal chemical components in iRoot BP, the biocompatibility test data for iRoot BP provides biocompatibility evidence that iRoot FS is non-mutagenic, does not cause an allergenic potential after multiple uses and has a good tolerance by subcutaneous tissue.

Consequently, the shelf life, bench and biocompatibility testing, provided evidence that iRoot FS's chemical and physical properties are substantially equivalent to iRoot BP.

CONCLUSIONS:

iRoot FS has the equivalent indications for use, comparable chemical composition, physical properties and performance specifications to iRoot BP. The additional chemical components found in iRoot FS were found to be safe and effective in iRoot SP and D-PBS. In addition, iRoot FS has comparable packaging containers and delivery system to iRoot BP Plus. Therefore, it is concluded that iRoot FS is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 3 2010

Mr. Quanzu Yang
President/CEO
Innovative BioCeramix Incorporated
1628 West 75th Avenue
Vancouver, British Columbia
Canada V6P 6G2

Re: K102867
Trade/Device Name: iRoot FS
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: October 27, 2010
Received: November 3, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 102867

INDICATIONS FOR USE

510(k) Number (if Known): _____

Device Name: iRoot FS

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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