



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 18, 2014

Innovative BioCeramix, Inc.
Quanzu Yang
President/CEO
1628 West 75th Avenue
Vancouver, BC
V6P 6G2 CANADA

Re: K130312
Trade/Device Name: iRoot FM
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Codes: KIF
Dated: June 26, 2014
Received: June 30, 2014

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 contact 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>. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



6.0 INDICATIONS FOR USE STATEMENT

The following document is included in this section:

- **INDICATIONS FOR USE STATEMENT**



7.0 510(k) SUMMARY

The following document is included in this section:

- **510(k) SUMMARY**

510(k) SUMMARY

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

SUBMITTER: Innovative BioCeramix Inc.
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CONTACT: Quanzu Yang

SUMMARY PREPARED: June 4, 2014

TRADE NAME: iRoot FM

COMMON NAME: Injectable Root Canal Filling Material

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

PREDICATE DEVICES:

- iRoot SP (K080917)
- BioAggregate (K063422)
- Diapex (K033585)

DEVICE DESCRIPTION: iRoot FM Injectable Root Canal Filling Material (iRoot FM) is a convenient premixed ready-to-use injectable, radiopaque, white hydraulic bioceramic paste developed for root canal filling applications. iRoot FM is an aluminum-free material based on a calcium silicate composition, which requires the presence of water to set. iRoot FM is packaged in a pre-loaded syringe and is supplied with disposable tips.

INTENDED USE:

For use in the treatment of root canals, or following pulpectomy, or for the apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.

These indications include application in:

- Apexification
- Periapical Lesions
- Root Resorption
- Temporary Root Filling
- Perforations
- Underdeveloped pulpless teeth

TECHNOLOGICAL CHARACTERISTICS:

The main chemical composition and performance specifications of iRoot FM is based on iRoot SP. Additional predicate devices include: iRoot FS and Diapex, each contains specific chemical components that are equivalent to those found in iRoot FM; providing evidence that these chemical components are utilized for medical device use.

iRoot FM and Diapex are designated for the equivalent dental applications. In addition, iRoot FM has a comparable delivery system and similar labeling to iRoot SP and Diapex.

NON-CLINICAL TESTS PERFORMED:

iRoot FM has undergone extensive bench and biocompatibility testing to provide evidence that iRoot FM's chemical and physical properties are substantially equivalent to iRoot SP. Bench tests included: flow, working time, setting time and radiopacity.

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

CONCLUSIONS:

iRoot FM demonstrates comparable chemical, physical, performance specifications and biocompatible properties to iRoot SP. iRoot FM's main chemical composition is based on iRoot SP. In addition, BioAggregate provides biocompatibility verification for iRoot FM. iRoot FM and Diapex have equivalent indications for use. Furthermore, iRoot FM has a comparable delivery system and similar labeling to iRoot SP and Diapex. Therefore, it is concluded that iRoot FM is substantially equivalent in safety and effectiveness to the predicate devices.