November 22, 2022

Innovative BioCeramix Inc.
℅ Quanzu Yang
CEO
Innovative BioCeramix, Inc.
101-8218 North Fraser Way
Burnaby, V3N039
CANADA

Re: K222992
Trade/Device Name: iRoot BP Root Repair Material BioAggregate Paste, iRoot FS Fast Set Root Repair Material, iRoot BP Plus Root Repair Material
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF,
Dated: September 28, 2022
Received: September 28, 2022

Dear Quanzu 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222992

Device Name

iRoot BP Root Repair Material BioAggregate Paste;
iRoot FS Fast Set Root Repair Material ;
iRoot BP Plus Root Repair Material

Indications for Use *(Describe)*

-Repair of Root Perforation
-Repair of Root Resorption
-Root End Filling
-Apexification
-Pulp capping
-Pulpotomy of primary teeth in the children (ages >2-12 years) and adolescent (ages >12-21 years).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Prepared on: 2022-09-22

Contact Details

K222992

21 CFR 807.92(a)(1)

Applicant Name	Innovative BioCeramix, Inc.
Applicant Address	101 - 8218 North Fraser Way Burnaby BC V3N0E9 Canada
Applicant Contact Telephone	6042216800
Applicant Contact	Dr. Quanzu Yang
Applicant Contact Email	quanzu@ibioceramix.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	iRoot BP Root Repair Material BioAggregate Paste; iRoot FS Fast Set Root Repair Material ; iRoot BP Plus Root Repair Material
Common Name	Root canal filling resin
Classification Name	Resin, Root Canal Filling
Regulation Number	872.3820
Product Code	KIF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K142178	ProRoot MTA	KIF
K082943	iRoot BP	KIF
K092715	iRoot BP Plus	KIF
K102867	iRoot FS	KIF

Device Description Summary

21 CFR 807.92(a)(4)

iRoot BP, iRoot FS, and iRoot BP Plus are a convenient ready-to-use fast setting white hydraulic premixed bioceramic paste. Which are developed for permanent root canal repair of root perforation and root resorption, and root end filling, apexification and pulp capping applications in adult and pediatric cases. The aforementioned products are an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. The products do not shrink during setting and demonstrate excellent physical properties. iRoot BP is packaged in a preloaded syringe, iRoot BP Plus is packaged in a preloaded container and iRoot FS is available both in syringe and container form. The devices have not changed from their respective predicate devices of iRoot BP(K082943), iRoot BP Plus(K092715), and iRoot FS(K102867).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

-Repair of Root Perforation
-Repair of Root Resorption
-Root End Filling

-Apexification
-Pulp capping
-Pulpotomy of primary teeth in the children (ages >2-12 years) and adolescent (ages >12-21 years).

Indications for Use Comparison 21 CFR 807.92(a)(5)

For the indications for use of the devices iRoot BP, iRoot BP Plus, and iRoot FS we are claiming substantial equivalence to the primary predicate device ProRoot MTA(K142178) as they have the same intended use. The indications for use of iRoot BP, iRoot BP Plus, and iRoot FS differ from the predicate devices iRoot BP(K082943), iRoot BP Plus(K092715), and iRoot FS(K102867). We are adding the use for the pulpotomy of primary teeth in children and adolescents. Since the new indication for use of the device only adds a new age group that the device can be used on with the existing functionality of pulpotomy/pulp capping it does not change the intended use of the device.

The use of iRoot Bp, iRoot BP Plus, and iRoot FS in the pulpotomy of primary teeth has been studied in many pieces of independent third-party, peer reviewed published medical literature. These studies show that the devices covered by this application are substantially equivalent to ProRoot MTA(K142178) in safety and effectiveness for the use on pediatric populations. As such we judged it appropriate to add the pulpotomy of primary teeth in children and adolescents as an indication for use. The summaries of some of the studies are included in the References section of this application

Technological Comparison 21 CFR 807.92(a)(6)

For the technological characteristics of the devices iRoot BP, iRoot BP Plus, and iRoot FS we are claiming substantial equivalence with the predicate devices iRoot BP(K082943), iRoot BP Plus(K092715), and iRoot FS(K102867) respectively. The devices covered in this application are identical to their corresponding predicate devices as reason for this application is only to change the indication for use to support pediatric populations.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

This proposal does not change any qualities of iRoot BP, iRoot BP Plus, and iRootFS. As such, it is identical to the respective predicate devices iRoot BP(K082943), iRoot BP Plus(K092715), and iRoot FS(K102867). The tests performed on the predicates were valid, so no other testing was done. In the attachments is the previous bench testing done on the submission of the predicate devices iRoot BP(K082943), iRoot BP Plus(K092715), and iRoot FS(K102867).

There were no clinical test that were performed by us at IBC. However iRoot BP and iRoot BP Plus and its predecessors have been on the international market for over 10 years now. Due to this there are many independent third-party studies that have been performed on iRoot BP and iRoot BP Plus which show their equivalence to MTA(K142178) for the purposes of pediatric applications as well as their safety and effectiveness in that specific use. The summaries of some of these studies are attached in the References section of this submission.

As the qualities of the proposed devices iRoot BP, iRoot BP Plus, and iRootFS have not changed from their respective predicate devices iRoot BP(K082943), iRoot BP Plus(K092715), and iRoot FS(K102867), they still strictly abide by the ISO 6876 and ANSI/ADA No. 57 and are also backed up by many independent third party clinical studies. With this we can conclude that the proposed the devices are both safe and effective as well as performing as well if not better then MTA(K142178).