May 31, 2023

Innovative BioCeramix, Inc.
Quanzu Yang
CEO
8218 North Fraser Way
Rm 101
Burnaby, BC V3N0E9
CANADA

Re: K231259
Trade/Device Name: iRoot SP Plus
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: April 18, 2023
Received: May 1, 2023

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,
Respiratory, ENT and Dental Devices
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)*

K231259

Device Name

iRoot SP Plus

Indications for Use *(Describe)*

• Permanent obturation of the root canal following vital pulp-extirpation
• Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.

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 - K231259

Contact Details

Applicant Name: Innovative BioCeramix Inc.
Applicant Address: 8218 North Fraser Way RM 101 Burnaby BC V3N0E9 Canada
Applicant Contact Telephone: (604)-221-6800
Applicant Contact: Dr. Quanzu Yang
Applicant Contact Email: quanzu@ibioceramix.com

Device Name

Device Trade Name: iRoot SP Plus
Common Name: Root canal filling resin
Classification Name: Resin, Root Canal Filling
Regulation Number: 872.3820
Product Code: KIF
510(k) Number: K231259

Legally Marketed Predicate Device

Predicate #	Predicate Trade name	Product Code
K080917	iRoot SP	KIF

Legally Marketed Reference Devices

Reference #	Reference Trade name	Product Code
K082943	iRoot BP	KIF
K032605	Metapaste Calcium Hydroxide With Barium Sulfate Temporary Root Canal Filling	KIF
K103190	ProFil Composites	EBF

Device Description Summary

iRoot SP Plus Root Canal Sealer (iRoot SP Plus) is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. iRoot SP 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 SP Plus demonstrates substantially equivalent physical properties to iRoot SP. iRoot SP Plus is packaged in a pre-loaded syringe and is supplied with disposable Tips.

Indications For Use

• Permanent obturation of the root canal following vital pulp-extirpation
• Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.

Indications For Use Comparison

The indications for use of iRoot SP Plus are equivalent to its primary predicate device of iRoot SP

Technological Comparison

iRoot SP Plus modifies iRoot SP by adding two additional materials to the primary predicate device. One of which is 3-(Trimethoxysilyl)propyl methacrylate, used as a coupling agent, for which we draw substantial equivalence with the reference device iRoot BP. The other being Barium silicate which will increase the radiopacity of the device, for which we draw substantial equivalence with the Barium Silicate found in the reference device ProFil and the Barium sulfate found in the reference device Metapaste.

Non-Clinical and/or Clinical Tests Summary & Conclusions

No Clinical tests were done specifically for this submission however, the predicate device iRoot SP has safetly been on the market since 2008 with over a million of global sales. iRoot SP also has clinical studies that have spanned up to four years in time over hundreds of clinical cases, which concluded that iRoot SP is safe and effective for use on patients. The non-clinical tests, based on ISO 6876 Third edition 2012-06-01, performed on both iRoot SP and iRoot SP Plus have shown that iRoot SP Plus is substantially equivalent to iRoot SP. Based on the evidence provided by the clinical and non-clinical tests we can say that iRoot SP Plus is safe and effective.