

K080917



510(k) SUMMARY

APR - 9 2008

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
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CONTACT: Dr. Quanzu Yang

SUMMARY PREPARED: January 18, 2008

TRADE NAME: iRoot SP

COMMON NAME: Root Canal Sealer

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

PREDICATE DEVICES:

- AH[®] Plus[™] Root Canal Sealer (K960548)

For specific chemical compositions:

- BioAggregate (K063422)
- Apexit[®] Root Canal Sealer (K893794)
- Exactech Resorbable Bone Paste (K020078)
- MBCP Gel[™] (K060732)

For delivery system:

- Diapex[®] (K033585)

DEVICE DESCRIPTION:

iRoot SP Root Canal Sealer (iRoot SP) is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. iRoot SP 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 does not shrink during setting and demonstrates excellent physical properties. iRoot SP is packaged in a pre-loaded syringe and is supplied with disposable Intra Canal Tips.



INTENDED 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.

iRoot SP is suitable for use in the single cone and lateral condensation technique.

TECHNOLOGICAL

CHARACTERISTICS: iRoot SP and AH[®] Plus[™] Root Canal Sealer are available as radiopaque pastes essentially designated for the equivalent dental applications and have comparable physical properties, performance specifications and share a specific chemical component.

The principal composition of iRoot SP is based on BioAggregate. Additional predicate devices include: Apexit[®] Root Canal Sealer, Exactech Resorbable Bone Paste and MBCP Gel[™], each contains specific chemical components that are equivalent to those found in iRoot SP, providing evidence that these chemical components are safe and effective for medical device use. Furthermore, iRoot SP and Diapex[®] have comparable delivery systems.

NON-CLINICAL TESTS PERFORMED:

iRoot SP has undergone extensive bench and biocompatibility testing to provide evidence that iRoot SP's physical-chemical properties are substantially equivalent to AH[®] Plus[™] Root Canal Sealer. Bench tests included: flow, working time, setting time, dimensional change following setting, solubility, radiopacity and film thickness.

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

CONCLUSIONS:

iRoot SP has the same indications for use, provides similar chemical, physical and biocompatible properties, and demonstrates comparable performance specifications to AH[®] Plus[™] Root Canal Sealer. iRoot SP's main chemical composition is based on BioAggregate and the additional chemical components in iRoot SP's composition were found to be safe and effective in Apexit[®] Root Canal Sealer, Exactech Resorbable Bone Paste and MBCP Gel[™]. In addition, iRoot SP has a comparable delivery system to Diapex[®]. Therefore, it is concluded that iRoot SP is safe, effective and substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2008

Innovative BioCeramix Incorporated
C/O Mr. Jay Y. Kogoma
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K080917

Trade/Device Name: iRoot SP Root Canal Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: March 31, 2008
Received: April 1, 2008

Dear Mr. Kogoma:

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.

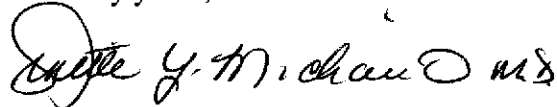
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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): K080917

Device Name: iRoot SP Root Canal Sealer

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.

iRoot SP is suitable for use in the single cone and lateral condensation technique.

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)

Susan Purdie

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080917