Vericom Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc
690 Roosevelt
Irvine, California 92620

December 20, 2017

Re: K170950
Trade/Device Name: Well-Root ST
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: November 20, 2017
Received: November 21, 2017

Dear Priscilla Chung:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170950

Device Name

Well-Root™ ST

Indications for Use *(Describe)*

Permanent sealing of root canal

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K170950)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 12/15/2017

1. **Applicant / Submitter:**

Vericom Co., Ltd.
48,Toegyegongdan 1-Gil, Chuncheon-Si,
Gangwon-Do, 200-944, Republic of Korea
Tel: +82-31-441-2881 Fax: +82-31-441-2883

2. **Submission Correspondent:**

Priscilla Chung
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. **Device:**

- **Trade Name:**
  Well-Root™ ST
- **Classification Name:**
  Root Canal Filling Resin
- **Classification regulation:**
  21CFR 872.3820
- **Product Code:**
  KIF

4. **Predicate Device:**

- Primary Predicate Device: AH PLUS ROOT CANAL SEALER (K960548) by Dentsply International
- Reference Device: iRoot SP (K080917) by Innovative BioCeramix, Inc.

5. **Description:**

Well-Root™ ST is a convenient premixed ready-to use composition which requires the presence of water to set and harden. The device is contained in a plastic syringe and the system includes a plunger, disposable tips, and a holder. We offer the following three types of package configuration. The raw materials including chemical composition of the Well-Root ST Type C (E) and Well-Root ST Type F (for sample) are the same. The only difference between the types are the net weight.

Package Type Name	Package Contents
Well-Root ST Type C	2g Syringe 1ea, Disposable Tip 20ea, Holder 1ea
Well-Root ST Type E	2g Syringe 1ea, Disposable Tip 15ea, Holder 1ea
Well-Root ST Type F(for sample)	0.5g Syringe 1ea, Disposable Tip 3ea, Holder 1ea

6. Indications for use:

Permanent sealing of root canal

7. Comparison to the Cleared Device

Well-Root™ ST has the same intended use as the predicate devices: AH PLUS ROOT CANAL SEALER (K960548) by Dentsply International and iRoot SP (K080917) by Innovative BioCeramix, Inc. The indication of the statement of the subject device is more simplified than the predicate devices but it does not contain new indications.

All of the devices confirm to ISO 6876 and are provided non-sterile. Both Well-Root™ ST and the iRoot SP (K080917) premixed ready-to-use injectable white hydraulic cement paste.

The difference between the Well-Root™ ST and the primary predicate device (AH PLUS ROOT CANAL SEALER) are delivery form and setting time. However, the differences do not affect to safety and effectiveness of product considerably. Delivery forms are just one of the attributes medical devices have for convenience of use. For the setting time, the test result of the subject device satisfies the requirement of the ISO 6876 and does not raise an issue of safety and/or performance.

We identified the reference device (iRoot SP) for similar raw materials and delivery form premixed ready-to use injectable paste. Well-Root ST is composed of lubricants, radiopaque agent and thickening agents as the reference device. Main materials, Calcium aluminosilicate compound of Well-Root ST is similar to Calcium silicate of the reference device. Also zirconium oxide as radiopaque agent is contained in both subject device and the reference device.

The results of the bench and the biocompatibility tests performed demonstrates that any of these differences do not raise a new question as to safety and effectiveness. Therefore, it is concluded that Well-Root™ ST is substantially equivalent to the predicate device.

	Subject Device	Primary Predicate Device	Reference Device
Trade Name	Well-Root™ ST	AH PLUS ROOT CANAL SEALER	iRoot SP
Manufacturer	VERICOM CO., LTD.	Dentsply International	Innovative BioCeramix, Inc.
510K Number	K170950	K960548	K080917
Product Code	KIF	KIF	KIF

Indications for Use	Permanent sealing of root canal	AH PLUS Root Canal Sealer is used for permanent sealing of root canals following established endodontic procedures.	• 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.
Raw materials	Insoluble, radiopaque material based on a calcium aluminosilicate compound containing: Lubricants Zirconium oxide Calcium sulfate dihydrate Titanium dioxide Inorganic glass(Calcium sodium phosphosilicate) Calcium aluminosilicate compound	Epoxy resin paste(Paste A) and the amine-containing paste(Paste B) containing: Paste A Bisphenol-A epoxy resin Bisphenol-F epoxy resin Calcium tungstate Zirconium oxide Silica Iron oxide pigments Paste B Dibenzyldiamine Aminoadamantane Tricyclodecane-diamine Calcium tungstate Zirconium oxide Silica Silicone oil	Insoluble, radiopaque material based on a calcium silicate compound containing: Thickening agent Zirconium oxide Filler Calcium phosphate monobasic Calcium hydroxide Calcium silicates(Tricalcium silicate, Dicalcium silicate)
Principle of operation	Well-Root™ ST is a convenient premixed ready-to-use injectable white hydraulic cement paste developed for permanent root canal filling and sealing applications. Well-Root™ ST is an insoluble, radiopaque material which sets and hardens with moisture providing from dentin tubules during hydration reaction. Well-Root™ ST is packaged in a pre-loaded syringe and is supplied with disposable tips.	AH Plus Root Canal Sealer consists of two components, the epoxy resin paste(Paste A) and the amine-containing paste(Paste B) portions which are mixed prior to insertion into the root canal. AH Plus Root Canal Sealer is two-component systems that react via an epoxide/amine chemical reaction to cause setting.	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 material which requires the presence of water to set and harden. iRoot SP is packaged in a pre-loaded syringe and is supplied with disposable tips.
Performance Standard Conformance	Conformed to ISO 6876	Conformed to ISO 6876	Conformed to ISO 6876

Biocompatibility	Yes	Yes	Yes
Use	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital
Delivery Forms	Single paste	Manual mixing of paste A and paste B	Single paste
Sterility	Non-sterile	Non-sterile	Non-sterile

8. Performance Data

The following testing was conducted on our subject device:

- Shelf Life: Appearance, ISO 6876 tests (Flow, Setting Time, Film Thickness)
- ISO 6876: Flow, Film Thickness, Solubility and disintegration, Radio-opacity, Working time
- ISO 10993-5 (Cytotoxicity), 10993-10 (Sensitivity-LLNA, GPMT), 10993-11 (Acute systemic Totoxicity), ISO 10993-3 (Genotoxicity-Bacterial reverse mutation(Ames), In vitro mammalian chromosomal aberration), ISO10993-6 (Implantation)

The subject device is different from the predicate devices in shelf life and raw materials, however, the test results provided in this submission supports that it is substantially equivalent to the predicate devices.

9. Conclusion

Based on documentation supplied with this submission, conclusions drawn from the testing results demonstrate that the subject device is substantially equivalent to our legally marketed predicate devices.