February 12, 2021

Maruchi
Jang Wook
CEO
2-208, Medical Industry Complex Bldg., 42-10, Taejanggongdan
Wonju-si, Gangwon-do 26311
REPUBLIC OF KOREA

Re: K201799
Trade/Device Name: CleaniCal
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: Class II
Product Code: EJK, KIF
Dated: December 28, 2020
Received: January 6, 2021

Dear Jang Wook:

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

Enclosure

4. INDICATION FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201799

Device Name
CleaniCal

Indications for Use *(Describe)*
CleaniCal is a Calcium Hydroxide paste that has a creamy consistency and is suitable for several indications including:
* Temporary disinfectant dressings in the obturation of root canals;
* Indirect pulp capping or management of deep caries lesions; or
* Direct pulp capping.

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.

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5. 510(k) SUMMARY

510(k) Summary

Date: June 15, 2020

1. SUBMITTER

MARUCHI

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2. DEVICE

·Trade Name: CleaniCal

·Common Name: Calcium hydroxide paste

·Classification Name: Liner, Cavity, Calcium hydroxide

·Regulation Number 872.3250

·Class: 2

·Classification Product Code: EJK

·Subsequent Product Code: KIF

3. Predicate Device

K060365, APEXCAL, Ivoclar Vivadent

K170175, ENDOSEAL MTA, MARUCHI

4. DEVICE DESCRIPTION

CleaniCal is a type of pre-filled syringe to Calcium Hydroxide Paste with a pH 12.3.

5. INDICATIONS FOR USE

CleaniCal is a Calcium Hydroxide paste that has a creamy consistency and is suitable

for several indications including:

* Temporary disinfectant dressings in the obturation of root canals;
* Indirect pulp capping or management of deep caries lesions; or
* Direct pulp capping.

6. PERFORMANCE TESTING (NON-CLINICAL)

The following test articles were tested based on the referenced standard. All the test results met the preset test criteria.

- Testing institution's method - Visual, Capacity, pH
- ISO 6876 - Package, Extraneous matter, Flow and Radio-opacity
- ISO 10993-5 - Cytotoxicity (Agar diffusion, MTT)
- ISO 10993-10 - Maximization test for delayed hypersensitivity (LLNA)
- ISO 10993-11 - Acute systemic toxicity
- ISO 10993-6 - Implantation (Subcutaneous tissue)
- ISO 10993-6 & ISO 10993-11 - Subacute systemic toxicity,
- ISO 10993-3 - Genotoxicity (Bacterial Reverse Mutation, & Mammalian Erythrocyte Micronucleus)

7. SUBSTANITAL EQUIVALENCE

	Proposed Device	**Predicate Device**	**Reference Device**	**Discuss/Justify the Differences**
510(k) Number	New	K060365	K170175	-
Trade Name	CleaniCal	APEXCAL	ENDOSEAL MTA	-
Manufacturer	MARUCHI	IVOCLAR VIVADENT, INC.	MARUCHI	-
Common Name	Calcium hydroxide paste	Calcium hydroxide paste	Root Filling Material	Equivalent
Classification Name	Liner, Cavity, Calcium hydroxide	Liner, Cavity, Calcium hydroxide	Resin, Root canal filling	Equivalent

Device Class	2	2	2	Equivalent
Product Code	EJK	EJK	KIF	Equivalent
Device Description	CleaniCal is a type of pre-filled syringe to Calcium Hydroxide Paste with a pH 12.3.	ApexCal is a creamy, radiopaque, ready-to-use calcium hydroxide paste with a pH above 12.5.	ENDOSEAL MTA is an endodontic sealer based on MTA, providing a root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals.	Equivalent
Indications for Use	CleaniCal is a Calcium Hydroxide paste that has a creamy consistency and is suitable for several indications including: * Temporary disinfectant dressings in the obturation of root canals; * Indirect pulp capping or management of deep caries	ApexCAL is a Calcium Hydroxide paste that has a creamy consistency and is suitable for several indications including: * Temporary disinfectant dressings in the obturation of root canals; * Indirect pulp capping or management of deep caries	* 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.	Equivalent

	lesions; or * Direct pulp capping.	lesions; or * Direct pulp capping.		
Intended user	Dental professional	Dental professional	Dental professional	Equivalent
Standards	ISO 6876	ISO 6876	ISO 6876	Equivalent
Chemical Composition	-Calcium hydroxide -Zirconium dioxide - Excipients (n-Methyl-2-pyrrolidone, Hypromellose)	- Calcium hydroxide - Bismuth carbonate - Excipients (polyethylene glycol, glycerine, water)	-Natural Pure Cement -Zirconium dioxide -Bismuth trioxide - Excipients (Bentonite Clay, n-Methyl-2-Pyrrolidone, Hypromellose)	The main component is same, but some other components are different. However, the biocompatibility and the performance test results supported that the subject device is substantially equivalent to the predicate devices.
Content of calcium hydroxide	30 %	29 %	-	Equivalent
pH	12.3	12.5	-	Equivalent
Liquid Formula	Paste type	Paste type	Paste type	Equivalent

Packaging	Pre-loaded syringe	Pre-loaded syringe	Pre-loaded syringe	Equivalent
Sterile	Non-sterile	Non-sterile	Non-sterile	Equivalent
Shelf Life	2 years	2 years	2 years	Equivalent

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

CleaniCal has the same indications for use and the principle of operations as the predicate devices. It is intended purpose as they are placed into the root canal as a calcium hydroxide paste which met the requirement according to ISO 6876. It has similar physical and biocompatible properties and demonstrates comparable performance specifications to the predicate devices.

The chemical compositions might slightly different from the predicate devices, both are used calcium hydroxide main composition as medicament, and additional component is used to make its appropriate workability.

The bench and biocompatibility testing performed demonstrates that any differences in their technological characteristics do not raise any new questions as to safety and effectiveness. Therefore, it is concluded that CleaniCal is substantially equivalent to the predicate devices. Hence, its equivalent is acceptable because it shows no clinically significant difference in the performance and safety to the device.