June 20, 2023

Vatech mcis Co., Ltd.
% Dave Kim
MTech Group
7505 Fannin St. Ste 610
Houston, Texas 77054

Re: K223029
Trade/Device Name: Perfit CL
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 22, 2023
Received: May 22, 2023

Dear Dave Kim:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
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.

510(k) Number *(if known)*
K223029

Device Name

Perfit CL

Indications for Use *(Describe)*

Perfit CL can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

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

K223029

The following 510(k) summary is being submitted as required by 21 CFR 807.92;

5.1 Submitter:

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Date Prepared: June 18, 2023

5.2 Device Identification

Device Trade Name	Perfit CL
Common Name	Coloring liquid for dental zirconium oxide ceramic
Classification Name, Number	Porcelain Powder for Clinical Use (21 CFR 872.6660)
Device Classification	II
Product Code	EIH

5.3 Predicated or legally marketed devices which are substantially equivalent

- Primary Predicate device: K173769, "DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid", manufactured by "DMAX Co, Ltd."

5.4 Device Description

This medical device is used to color the zirconia pre- sintered body, and it is a color solution that makes the color similar to natural teeth by using a brush and immersion.

5.5 Statement of Indication for use

Perfit CL can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.

5.6 Non-clinical Test Conclusion

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- Shelf- Life Test
- ISO 10993-3- Genotocixity (Ames test) & Genotocixity (Micronucleus)
- ISO 10993-5- Cytotoxicity
- ISO 10993-10 - Sensitization & Irritation
- ISO 10993-11 – Acute systemic toxicity (Oral)
- Other bench testing- Appearance, Volume, Packaging, Dissolution analysis, Color stability

Bench test results allowed to conclude that Perfit CL is substantially equivalent to the predicate devices for its intended use.

5.7 Clinical Test Conclusion

Clinical testing was not required for this submission.

5.8 Technical Characteristics and Substantial Equivalence

The following table shows similarities and differences of Packaging Volume, Shade and Storage Conditions between our device and the predicate devices.

Table 1. General Device Characteristics Comparison Table

No.	Item	Subject Device	Predicate Device	Remark
1	Device Name	Perfit CL	DMAX coloring liquid Chang's liquid Confident coloring liquid CAMeleon coloring liquid	-
2	Manufacturer	Vatech mcis Co., Ltd	DMAX Co., Ltd.	-
3	510(k) Number	K223029	K173769	-
4	Product Code	EIH	EIH	-
5	Class	II	II	-
6	Review Panel	Dental	Dental	-
7	Technology	Water-based with inorganic pigments	Water-based with inorganic pigments	Same as predicate
8	Indications for Use	Perfit CL can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients	DMAX coloring liquid, Chang's liquid, Confident coloring liquid, and CAMeleon coloring liquid can be used as an accessory to zirconium dioxide dental restorative material to provide individual tooth (or teeth) shading. It is intended to be used solely by certified dental technicians for fabrication of zirconium dioxide restorations for individual dental patients.	Same as predicate
9	Principles of Operation	Brush or immerse zirconia ceramic with coloring liquid before sintering	Brush or immerse zirconia ceramic with coloring liquid before sintering	Same as predicate

10	Prescription Use	Prescription only	Prescription only	Same as predicate
11	Target population	General, mostly adults	General, mostly adults	Same as predicate
12	Type of Packaging	Liquid container	Liquid container	Same as predicate
13	Packaging Volume(ml)	20 and 50mL	15,20,30,40 and 100mL	No significant difference. The dose is different but it can be differentiated depending on experts' determination. That is, dose is not relevant to clinical performance and safety.
14	Shade	27 colors	45 colors	No significant difference. The shade is different but it can be differentiated depending on experts' determination. That is, dose is not relevant to clinical performance and safety.
15	Storage Conditions	2 years at 0-25 °C	1 year at 2-28 °C	No significant difference. The storage temperature is a little different but the storage temperature does not cause any clinical performance and safety issue will not be caused by the storage temperature if stored at the recommended storage temperature.
16	General Physical Form	Liquid	Liquid	Same as predicate
17	Sterility	Non-Sterile	Non-Sterile	Same as predicate
18	pH	5.5~8.0	5.5~8.0	Same as predicate
19	Boiling Point	100°C	100°C	Same as predicate
20	Density	1.00~1.10 g/cm^3	1.00~1.10 g/cm^3	Same as predicate
21	Specific Gravity (Relative Density)	1.00~1.10	1.00~1.10	Same as predicate
22	Solubility in Water	100%	100%	Same as predicate
24	Biocompatibility Testing	Tested to ISO 10993-1	Tested to ISO 10993-1	Same as predicate
25	Performance Testing	Tested to ISO 6872	Tested to ISO 6872	Same as predicate

The subject device is substantially equivalent to the predicate device, DMAX coloring liquid, Chang's liquid, Confident coloring liquid, CAMeleon coloring liquid, (K173769) made by DMAX Co., Ltd. Both the device has the same indications for Use and technological characteristics. They even have the same pH, boiling point, density and specific gravity range. Both devices are soluble in water. The raw material composition rate might be different between the devices, however, the subject device meets the requirements ISO 10993, therefore, this difference would not raise a question in substantial equivalence.

5.9	**Conclusion**	Based on the testing results, Vatech mcis Co., Ltd concludes that the subject device is substantially equivalent to the predicate device.
5.10	**Declarations**	This summary includes only information that is also covered in the body of the 510(k). This summary does not contain any puffery or unsubstantiated labeling claims.