May 25, 2023

Guangzhou Beogene Biotech Co., Ltd
℅ Tracy Che
Registration engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center
No. 3101-90, Qianhai Road
ShenZhen, GuangDong 518052
CHINA

Re: K222891
Trade/Device Name: Dental Desensitizer
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: March 29, 2023
Received: March 29, 2023

Dear Tracy Che:

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.

510(k) Number *(if known)*
K222891

Device Name
Dental Desensitizer

Indications for Use *(Describe)*
The Dental Desensitizer is a colorless transparent gel that is applied to the sensitive part of the tooth to form a film, sealing the exposed dentin tubules and relieving dentin allergy. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity.

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

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information

510 (k) owner's name:	Guangzhou Beogene Biotech CO., Ltd
Address:	Second floor, Building C, Self-compiled (1) Building, No.2 Ruitai Road, Huangpu District, Guangzhou, China
Contact person:	Duan Qiangqiang
Phone number:	+86-16626708885
Fax number:	+86-020-32029939
Email:	2885151672@qq.com
Date of summary prepared:	2023-3-29
Reason for the submission:	New device, there were no prior submissions for the device.

(2) Proprietary name of the device

Trade name/Model:	Dental Desensitizer
Common name	Tooth Desensitizer
Regulation name:	Varnish, Cavity
Regulation number:	21 CFR 872.3260
Product code	LBH
Review panel:	Dental
Regulation class:	Class II

(3) Predicate device

Sponsor	Ultradent Products, Inc.
Device Name and Model	UltraEZ Desensitizing Gel
510(k) Number	K061438
Product Code	LBH
Regulation Number	21 CFR 872.3260
Regulation Class	II

(4) Description/ Design of device

Dental Desensitizer is a sustained release, 3% potassium nitrate and 0.11% weight by weight fluoride ion, viscous gel. This product is designed to be used together with a custom-fabricated tray.

(5) Intended use/ Indications for use

The Dental Desensitizer is a colorless transparent gel that is applied to the sensitive part of the tooth to form a film, sealing the exposed dentin tubules and relieving dentin allergy. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity.

(6) Materials

Component name	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Dental Desensitizer	External communicating device: tissue/bone/dentin	Permanent contact >30 d

The Dental Desensitizer has passed biocompatibility tests. Details can be seen in "Biocompatibility Discussion".

(7) Technological characteristics and substantial equivalence

Item	Subject device	Predicate device	Remark
Trade name	Dental Desensitizer	UltraEZ Desensitizing Gel	/
510 (k) number	/	K061438	/
Regulation number	21 CFR 872.3260	21 CFR 872.3260	Same
Regulation name	Varnish, Cavity	Varnish, Cavity	Same
Product code	LBH	LBH	Same
Class	II	II	Same
Indications for use/ Intended use	The Dental Desensitizer is a colorless transparent gel that is applied to the sensitive part of the tooth to form a film, sealing the exposed dentin tubules and relieving dentin allergy. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity	The UltraEZ Desensitizing Gel provides a film-like varnish for sensitive teeth, sealing dentinal tubules of over exposed dentin and other exposed areas where post-operative or other dentin sensitivity is a concern. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity	The description is different compared to the predicate device, it is actually the same.
Prescription or OTC	Prescription Use	Prescription Use	Same
Scope of use	Hospital, dental office, or home treatment	Dental office or home treatment	Same

Design	Designed to be used together with a custom-fabricated dental tray.	Designed to be used in a custom-fabricated dental tray.	Same
Materials	3% Potassium Nitrate; 0.11% w/w Fluoride Ion	3% Potassium Nitrate; 0.11% w/w Fluoride Ion	Same
Appearance	Colorless, odourless, transparent gel, no visible impurity	Colourless, Odourless, Gel	Same
PH-value	6-7.5	6-7.5	Same
Recommended contact time	Treatment 15-60 mins	Treatment 15-60 mins	Same
Device description	Immediate physical blockage of dentinal tubules to eliminate painful sensitivity.	Immediate physical blockage of dentinal tubules to eliminate painful sensitivity.	Same
Biocompatibility	Passed the tests as per ISO 10993-5, ISO 10993-10 and ISO 10993-11 (Cytotoxicity, sensitization, irritation, acute systemic toxicity)	Passed the tests as per ISO 10993-5 and ISO 10993-10 (Cytotoxicity, sensitization, irritation)	Similar
Sterility	Non-sterile	Non-sterile	Same

Conclusion:
Based on the above analysis, the Dental Desensitizer is substantial equivalent to the predicate device.

(8) Non-clinical studies and tests performed

Non-clinical testings have been conducted to verify that the Dental Desensitizer meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device.

Performance Test Report

A performance verification test was performed to analyze treatment effect of Dental Desensitizer during patient treatment, and to validate that the output meets design specifications and demonstrate that the treatment effect of Dental Desensitizer is expected compared to the predicate device. Properties evaluated include appearance, loading capacity, potassium content, fluoride content, total heavy metal content, arsenic content, PH value, microbial limit, and dentin tubule occlusion comparative test.

Shelf Life Test Report

Shelf life testing was conducted by evaluating the physical properties of the device to confirm a shelf life at room temperature of 24 months.

Biocompatibility

A biocompatibility discussion was conducted. The Dental Desensitizer has been tested and shown to be compliant with the following standards:

- ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization
- ISO 10993-11, Biological Evaluation of Medical Devices - Part 11: Tests For Systemic Toxicity

(9) Clinical studies and tests performed

Clinical studies and tests were not conducted.

(10) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Dental Desensitizer is to be concluded substantial equivalent to its predicate devices.