August 9, 2022

DenMat Holding, LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K222357
Trade/Device Name: DenMat Glutaraldehyde Desensitizer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin tooth bonding agent
Regulatory Class: Class II
Product Code: KLE, LBH
Dated: August 3, 2022
Received: August 4, 2022

Dear Prithul Bom:

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 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)*
K222357

Device Name
DenMat Glutaraldehyde Desensitizer

Indications for Use *(Describe)*
• To reduce pain in exposed cervical areas not requiring restoration.
• To alleviate dentinal sensitivity after preparation of teeth to receive indirect or direct restorations.

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."

5. 510K Summary K222357

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Den-Mat Holdings, LLC is hereby submitting this 510(k) summary.

Submitter [510K Owner]

Den-Mat Holding, LLC
1017 W. Central Avenue
Lompoc, CA 93436

Company Contact

Murisa Woodlin
Regulatory Affairs Coordinator
P: 805-346-3700 ext. 2933
E: mwoodlin@denmat.com

Submitted Device Information

Trade Name: DenMat Glutaraldehyde Desensitizer
Common Name: Desensitizer
Classification Name: Agent, Tooth Bonding, Resin

Classification Information

Classification: Class II
Classification Regulation: 21 CFR 872.3200
Classification Product Code: KLE

Legally Marketed Predicate Devices

DenMat Glutaraldehyde Desensitizer is manufactured by Den-Mat Holdings, LLC (DenMat) is substantially equivalent to the following device currently in commercial use:

- Device Trade Name: GLUMA Desensitizer
- Manufacturer: Heraeus Kulzer
- Address: 4315 S. Lafayette Blvd, South Bend, IN 46614
- 510(k) number: K962812
- Product Code: KLE

Submitted Device Description

DenMat Glutaraldehyde Desensitizer is an aqueous, 5% glutaraldehyde-based desensitizer with 35% Hydroxy-ethyl Methacrylate (HEMA - a pre-primer resin) designed for use with 4th and 5th generation adhesives. DenMat Glutaraldehyde Desensitizer works by coagulating the plasma proteins contained within the dentinal tubule fluid. This coagulation forms an initial “plug” (which can be seen to a depth of 200 microns[1]), eliminating the movement of fluid within the tubules—the root cause of dentinal sensitivity. In clinical studies, glutaraldehyde has consistently been shown to significantly decrease sensitivity[2] on hypersensitive teeth without affecting bond strength between treated surfaces and controls[3]. Glutaraldehyde has shown little or no effect on retention on crowns luted with zinc phosphate, glass ionomer, and resin-modified glass ionomer cements[4], and is one of few desensitizers that will not adversely affect bond strengths of resin cement to dentin[5].

References:
1. Shupach P, Lutz, Finger WJ. Closing of dentinal tubules by Gluma desensitizer. Eur J Oral Sci. 1997; 105:414-421. 2. Dall'Orologio GD, Maferrari S. Desensitizing effects of Gluma on hypersensitive teeth. Am J Dent 1993; 6:283-286. 3. Reinhardt JW, Stephens NH, Fortin, D. Effect of Gluma desensitization on dentin bond strength. Am J Dent 1995; 4:170-172. 4. EJ Swift Jr., AH Loyd, DA Fenton. The effect of resin desensitizing agents on crown retention. JADA Vol.128, Issue 2; 195-200. 5. Cobb, DS, Reinhardt, JW, Vargas, MA. Effect of HEMA-containing dentin desensitizers on shear bond strength of a resin cement. Am J Dent. 1997; 2:62-65.

Intended Use Environment

The device use environment is intended for the dental offices/dental work environment.

Intended Use/Indications for Use

· To reduce pain in exposed cervical areas not requiring restoration.
· To alleviate dentinal sensitivity after preparation of teeth to receive indirect or direct restorations.

Substantial Equivalence

DenMat Glutaraldehyde Desensitizer is substantially equivalent to the predicate device, in which the basic features and intended uses are essentially the same.

The differences between the legally marketed device and the subject device, DenMat Glutaraldehyde Desensitizer differences are minor and adequately supported by bench performance testing, as appropriate.

The GLUMA Desensitizer and DenMat Glutaraldehyde Desensitizer differences are the following:

- GLUMA Desensitizer provided in 5mL bottles only, DenMat Glutaraldehyde Desensitizer comes in 5mL and 10mL bottles.
- Changes between the GLUMA Desensitizer and the DenMat Glutaraldehyde Desensitizer is the name of the 510(k) owner/holder/submitter and the trade name of the devices.

The ingredients and packaging (5mL LDPE and chipboard carton) are identical. The only difference is the label format.

DenMat Glutaraldehyde Desensitizer system is substantially equivalent in design, manufacturing materials, intended use, and principles of operation to GLUMA Desensitizer, and raises no new issues of safety or effectiveness.

COMPARISION OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE
The similarities and differences between the predicate and proposed desensitizers are:

Property or Characteristic	Proposed Device – Den-Mat Holdings, LLC. DenMat Glutaraldehyde Desensitizer	Predicate Device – Heraeus Kulzer GLUMA Desensitizer K962812	Comments
Device Classification Name	Agent, Tooth Bonding, Resin	Agent, Tooth Bonding, Resin	Same
Product Code	KLE	KLE	Same
Indications for Use	·To reduce pain in exposed cervical areas not requiring restoration. · To alleviate dentinal sensitivity after preparation of teeth to receive indirect or direct restorations.	· To reduce or even eliminate pain in exposed cervical areas not requiring restoration. · To alleviate or prevent dentinal sensitivity after preparation of teeth to receive indirect or direct restorations.	Same
Material	Water, Glutaraldehyde and HEMA (Hydroxy Ethyl Methacrylate)	Water, Glutaraldehyde and HEMA (Hydroxy Ethyl Methacrylate)	Same
Prescription or OTC	Prescription	Prescription	Same
Mode of Action	It achieves its effects by precipitation of plasma proteins, which reduces dentinal permeability and occludes the peripheral dentinal tubules. This inhibits the flow of fluid through the tubules which is the cause of sensitivity.	It achieves its effects by precipitation of plasma proteins, which reduces dentinal permeability and occludes the peripheral dentinal tubules. This inhibits the flow of fluid through the tubules which is the cause of sensitivity.	Same

Summary of Substantial Equivalence:

Based on the information presented in this submission, Den-Mat Holdings, LLC concludes that DenMat Glutaraldehyde Desensitizer is substantially equivalent to the predicate device in regard to indications for use, material and mode of action.

Non-clinical Testing Completed:

Viscosity and pH non-clinical tests were performed to demonstrate the substantial equivalence of DenMat Glutaraldehyde Desensitizer to GLUMA Desensitizer and demonstrate the comparability of handling and chemistry similarities between the two products. The values are shown below.

The data shown below for Shear Bond strength demonstrates application DenMat Glutaraldehyde Desensitizer shows that it does not affect the shear bond strength to adhesive.

DenMat Glutaraldehyde Desensitizer- Viscosity Testing

Equipment and model: AR2000 Rheometer (TA Instruments)	
Measurement	Viscosity **η** (cps)
1	2.802
2	2.922
3	2.983
Ave ± SD	2.902 ± 0.09

Table 1: Viscosity of GLUMA[1]

Desensitizer	**Manufacturer**	**Mean η (cps)**	**StDev η (cps)**
GLUMA	Heraeus Kulzer	2.95	0.07

The desired viscosity value is between 2-4 cps. The 2-4 cps specification is based on the following:

A dentin desensitizer which has similar viscosity to that of water which will perform as desired, penetrating deeply into the dentinal tubules well.

Viscosity of water in room temperature is about 0.9 cps and an acceptable range of desensitizer's viscosity is estimated to be 2-4 cps considering that a typical desensitizer is composed of 60% water, 35% HEMA, and 5% glutaraldehyde. [1]

Glutaraldehyde crosslinks proteins in the dentinal fluid to create a barrier deep into the tubules. Further, standard dentinal adhesives with their long resin tags can provide tubular occlusion and thereby alleviates sensitivity. In some cases the adhesives are not sufficient by themselves to do so, hence there is need for an additional desensitizer prior to the application of the adhesive.

DenMat Glutaraldehyde Desensitizer- PH Testing

Acceptable pH:
A desirable characteristic of a dentin desensitizer is that it should not be excessively acidic. This is to ensure that the integrity of the mineral portion of the dentin is not compromised. The target specification for an acceptable pH range is 3.2 – 4.4.

Equipment and model: Fisher Scientific Accumet Model 15	
Measurement sample	pH
1	3.570
2	3.570
3	3.560
Ave ± SD	3.563 ± 0.006

Table 2: pH measurement of GLUMA[1]

Desensitizer	**Manufacturer**	**pH1**	**pH2**	**pH3**	**Mean**	**StDev**
GLUMA	Heraeus Kulzer	3.60	3.59	3.59	3.59	0.01

GLUMA pH range: 3-4[2].

The data provided for pH and Viscosity demonstrate that DenMat Glutaraldehyde Desensitizer and the predicate device, GLUMA Desensitizer, compare favorably and justify the use of the predicate device as a comparator.

Reference:
[1] CALM-IT Desensitizer – Technical Manual, Rev. 4/23/08 Copyright © 2008 Dentsply International, pages 10-11.
[2]FAQs_GLUMA_Desensitizer_0519_WEB.pdf

Shear Bond Strength Test results:

Specimen #	Shear Bonding Strength without DenMat Glutaraldehyde Desensitizer (MPa)	Shear Bonding Strength with DenMat Glutaraldehyde Desensitizer (MPa)
1	6.14	10.34
2	5.40	9.27
3	12.70	14.64
4	14.23	5.58
5	7.92	6.61
6	5.37	13.63
7	5.07	14.90
8	11.05	7.94
9	8.49	9.99
		10.32
Ave ± SD	8.49 ± 3.42	10.32 ± 3.22

DenMat Glutaraldehyde Desensitizer does not interfere bonding of total etch adhesives on dentin.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate devices.