K093575

Heraeus

Technical File

MAR - 5 2010

Summary of safety and effectiveness of the desensitizing agent
Gluma® Desensitizer PowerGel

1. Submitter name

Heraeus Kulzer, LLC
300 Heraeus Way
South Bend, Indiana 46614

Contact person: Cheryl V. Zimmerman
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Date summary prepared: March, 02, 2010

2. Name of the device:

Gluma Desensitizer PowerGel
The product is Regulatory Class II and the product code KLE
It is used as Desensitizer.

The GMDN number is 34782 and the description is Desensitizer, Dental bonding agent, polymer based, the UMDS number is 34782 and the description is Klebemittel.

3. Substantially equivalence

Gluma Desensitizer PowerGel (Project Name IGLU) is a revised version of the product Gluma Desensitizer (K962812). The main components and their ratio in IGLU and Gluma Desensitizer are similar. IGLU contains additionally filler particles and pigments to realize a green opaque coloured gel or paste. These changes will lead to an easier and safer handling of Gluma Desensitizer PowerGel when compared to Gluma Desensitizer.

4. Description of the device

GLUMA Desensitizer PowerGel is used for treatment of hypersensitive dentine. The product should be applied only on dentin with a sufficient remaining pulpal wall. 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.
Gluma® Desensitizer PowerGel is a product for a simple and safe application. It's viscous gel like consistency leads to an easy and save application. Uncontrolled flowing from the tooth is avoided and subsequent irritation of soft tissue should be reduced. The opaque, green colour has a good visible contrast to the tooth and the mucosa so that the operator could easily see where he has applied the product.
The physical properties of Gluma® Desensitizer PowerGel especially the consistency were determined in accordance with internal specifications. The results have shown good and sufficient properties of Gluma® Desensitizer PowerGel according to the specification.

The product will be put in the market in 1,8 ml Syringe with a content of 1 g product.

The specification of the product is as followed:

Appearance	Green, homogenous Gel, without impurities	
Composition tested with GC	active substance	4,0 - 6,0 %
	Cross linking agent	according to referenceViscosity
1000 - 3000 mPas		

5. Intended use

Gluma® Desensitizer PowerGel is an aqueous, viscous gel of Glutaraldehyd, HEMA, colloidal silica and pigments. It achieves its effect by precipitation of plasma proteins, which reduces the dentinal permeability and occludes the peripheral dentinal tubules. This occlution reduces the liquid movement within the tubules. This liquid movement is the cause of sensitivity.

The intended use of the product is as follows:

- Reduction or even elimination of pain in exposed cervical areas that do not require restoration
- Allevation or prevention of dentinal sensitivity after preparation of teeth to receive fixed prosthesis or restorations

Contra indication

Gluma Desensitizer PowerGel must not be used

- If the necessary precautions cannot be taken or the stipulated application technique is not possible
- In cases of known or suspected allergy to Gluma Desensitizer Powergel. If an allergy is suspected it is recommended to carry out an allergy test prior to treatment
- If the pain is due to pulpitis
- If the pulp is perforated or the dentine adjacent to the pulp is perforated.

6: Summaries

a: See point 3

b: (1) Nonclinical- tests: In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1.

The biological compatibility of Gluma® Desensitizer PowerGel was verified in accordance with the international standard.
The biocompatibility of Gluma® Desensitizer PowerGel in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk-relation has been judged as positive.

(2) Clinical Evaluation

In accordance with the medical Device directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes a clinical evaluation in accordance with MEDDEV 2.7.1., which is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks. Therefore, any clinical evaluation is part of the compulsory risk management process according to EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device.

On this background, the clinical evaluation was performed in order to comply with the current European medical device legislation, in particular with MEDDEV 2.7.1. This critical evaluation followed the procedures outlined in the corresponding clinical evaluation plan.

Gluma® Desensitizer PowerGel is a Desensitizer, which is generally classified as a class IIa medical device under the Medical Device Directive 93/42/EEC.

The material is used for the treatment of hypersensitive dentine, intended for long-term application.

Considering the evaluated scientific data and technical results for Gluma® Desensitizer PowerGel it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry. Therefore, a positive benefit versus risk ratio can be stated by the expert for Gluma® Desensitizer PowerGel, provided that the product applied in accordance with its intended use as outlined in the manufacturer's instruction for use.

Considering the evaluated scientific data for dental desensitizers in general as well as for comparator products, it is concluded, that Gluma® Desensitizer PowerGel will exhibit the claimed clinical performance when applied according to the intended use as follows:

Gluma® Desensitizer PowerGel is used for treatment of hypersensitive dentine. The product should be applied only on dentin with a sufficient remaining pulpal wall.

Due to the ingredients of Gluma® Desensitizer PowerGel, such as hydroxyethylmethacrylate and glutardialdehyde, warnings on a likely dermal, eye and respiratory irritating potential and on a likely dermal and respiratory sensitizing potential have to be included in the respective instructions for use.

Nevertheless, the potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry. Therefore, a positive benefit versus risk ratio can be stated for Gluma® Desensitizer PowerGel, provided that the product is applied as outlined in the manufacturer's information for use.

The clinical evaluation report was prepared in accordance with MEDDEV 2.7.1 and followed the provisions of the corresponding clinical evaluation plan.

(3) Conclusion

A positive benefit versus risk ratio can be stated by the experts for Gluma® Desensitizer PowerGel, provided that the product applied in accordance with its intended use as outlined in the manufacturer's instruction for use for the clinical and the non-clinical test results.

(c) 510 (k) summary

The risk potential of the Desensitizer Gluma® Desensitizer PowerGel was proved considering the current composition. All properties of the product were verified successfully.

The biological compatibility of the desensitizing material was investigated to evaluate the toxicological risk. A toxicological evaluation report has confirmed that the product Gluma® Desensitizer PowerGel meets the requirements of the DIN EN ISO 10993 standard. The results were discussed in a Biocompatibility Evaluation Report and the benefit/risk-relation has been judged as positive.

The physical properties of Gluma® Desensitizer PowerGel were determined in accordance with internal standards. The results have shown good properties of Gluma® Desensitizer to the specification.

Based on the results of the clinical evaluation report it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighted against their benefits in dentistry.

The risk analysis (according to DIN EN ISO 14971) was carried out for Gluma® Desensitizer PowerGel and showed that the application of Gluma® Desensitizer PowerGel could be considered to be safe.

Gluma® Desensitizer PowerGel meets all requirements relevant for dental desensitizing material in accordance with the Medical Device directive 93/42/EEC and national European medical device legislation. Based on the actual facts Gluma® Desensitizer PowerGel could be evaluated to be effective and safe with its intended use as outlined in the manufacturer's instruction for use.

Dormagen, 02.03.2010

i.A.
Dr. Marcus Hoffmann

i.A.
Annegrete Wegner

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 5 2010

Ms. Cheryl V. Zimmerman
Manager, Quality Operations and Compliance
Heraeus Kulzer, Incorporated
300 Heraeus Way
South Bend, Indiana 46614

Re: K093575
Trade/Device Name: Gluma Desensitizer PowderGel
Regulation Number: 21CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: February 4, 2010
Received: February 12, 2010

Dear Ms. Zimmerman:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K093575_____

Device Name: ___**Gluma Desensitizer PowerGel**_____

Indications for use:

- Reduction or even elimination of pain in exposed cervical areas that do not require restoration.
- Alleviation or reduction of dentine sensitivity after preparation of teeth to receive fixed prosthesis or restorations.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Bedi DDS for Dr K. P. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093575