July 29, 2019

Ivoclar Vivadent, AG
% Lori Aleshin
Director of Quality & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K190339
Trade/Device Name: Helioseal F Plus
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit And Fissure Sealant And Conditioner
Regulatory Class: Class II
Product Code: EBC
Dated: April 23, 2019
Received: April 30, 2019

Dear Lori Aleshin:

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,

Srinivas Nandkumar, Ph.D.
Acting 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

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)*
K190339

Device Name
Helioseal® F Plus

Indications for Use *(Describe)*
Helioseal F Plus is used to seal fissures, pits and foramina caeca.

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

K190339

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Date Prepared: February 8, 2019

Proprietary Name: **Helioseal® F Plus**

Classification Name: Sealant, pit and fissure, and conditioner Resin (872.3765) (Classification Code EBC)

Predicate Device: Helioseal® F (K932078) by Ivoclar Vivadent, AG

Device Description: **Helioseal® F Plus** is a light-curing, white shaded fissure sealant featuring fluoride release. Helioseal F Plus is supplied in either a syringe or cavifil delivery form. The fissure sealant is composed of dimethacrylates. In the handling technique, the dental professional will clean the enamel surface to be sealed, isolate the working field, conditioning is performed, a thorough rinse and dry to remove the conditioner, before the application of Helioseal F Plus to the tooth surface.

Indications for Use: Helioseal F Plus is used to seal fissures, pits and foramina caeca.

Comparison to Predicate: The primary predicate devices to which Helioseal F Plus has been compared is Ivoclar Vivadent, AG Helioseal F (K932078).

Device	Ivoclar Vivadent AG: Helioseal F (K932078)	Ivoclar Vivadent: Helioseal F Plus
Indications for Use	Helioseal F is used to seal pits, fissures and foramina caeca.	Helioseal F Plus is used to seal pits, fissures and foramina caeca.
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	**Contraindication:** - If the patient is known to be allergic to any of the materials ingredients. - If a dry working field cannot be established. **Side effects:** - In individual cases, contact allergies may occur according to today's standard of knowledge, systemic side effects are not known **Warning**: Avoid contact of unpolymerized material with skin/mucous membrane or eyes. Unpolymerized Helioseal F may cause slight irritation and, in rare cases, may lead to a sensitization against methacrylates. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. **Special notes:** - If Helioseal F is applied from the Cavifil directly in the mouth of the patient, we recommend using this Cavifil only for one patient due to hygienic reasons (prevention of cross-contamination between patients). The same applies to the application tips of the syringe - Syringes or Cavifils should not be disinfected with oxidizing disinfection agents	**Contraindication:** - If a patient is known to be allergic to any of the ingredients of Helioseal F Plus, it must not be used -The use of Helioseal F Plus is contraindicated if a dry working field cannot be established. **Side effects**: - In rare cases, components of Helioseal F Plus may lead to sensitization. The product must not be used in such cases. **Warning**: Avoid contact of unpolymerized Helioseal F Plus with skin/mucous membrane or eyes. Unpolymerized Helioseal F Plus may cause slight irritation and, in rare cases, may lead to sensitization against methacrylates. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates. **Special notes:** - For single use only. If Helioseal F Plus is applied directly in the mouth of the patient, we recommend using the Cavifil or the tips of the syringe only for one patient due to hygienic reasons (prevention of cross-contamination between patients) - Do not disinfect syringes with oxidizing disinfectants - In order to prevent air bubbles in the syringe, do not pull back the plunger of the syringe during or after the treatment
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	Contraindications, Side effects, Warning and Special note of the two products are basically the same, there is a slight difference in the wording. The indications for both devices are the same, therefore the devices are substantially equivalent.	
Technology	Helioseal F is a light-curing, white shaded fissure sealant featuring fluoride release.	Helioseal F Plus is a light-curing, white-shaded fissure sealant featuring fluoride release.
Summary of Technology	No difference.	
Delivery forms/dosage	The sealant is available in syringes (1.25g) and cavifil (0.1g)	The sealant is available in syringes (1g and 1.25g) and cavifil (0.1g)
Summary of Delivery forms/dosage	The predicate device is available in 2 delivery forms, but only one size syringe. One less than Helioseal F Plus. The delivery forms are the same.	

Storage Conditions	30 months at 2-28 °C / 36-82 °F, Close Helioseal F syringe immediately after use. Do not use the material after the indicated date of expiration. Syringes or Cavifils should not be disinfected with oxidizing disinfection agents.	24 month at 2-28 °C / 36-82 °F, Close the syringe immediately after use. Exposure to light may lead to premature polymerization. Do not use Helioseal F Plus after the indicated date of expiration.
Summary of Storage Conditions	The recommended shelf life is shorter for the new product, as less data is currently available. The shelf life will be extended on the basis of continuing real-time studies.	
Principles of Operation	**Application:** - Thoroughly clean the enamel surface to be sealed. - Isolate the working field, preferably with a rubber dam - Apply an etching gel, e.g. Email Preparator, and let it react for 30 to 60 seconds - Rinse thoroughly. - Dry with water- and oil-free air.the etched enamel should have a mat white appearance. Avoid contamination of the etched surface with saliva - Apply Helioseal F directly with the disposable cannula or a disposable brush, and disperse - Wait for approx. 15 seconds. Then cure the sealant with a suitable polymerization light (e.g. bluephase) for 20 seconds - Check seal and occlusion	**Application:** - Clean the enamel surface: Thoroughly clean the enamel surface to be sealed (e.g. Proxyt). - Isolation: Isolate the working field, preferably with a rubber dam (e.g. OptraDam Plus) - Conditioning: Conditioning is performed according to the Instructions for Use of the product in use. Ivoclar Vivadent recommends the use of a low-viscosity phosphoric acid gel. - Rinse thoroughly and dry - Thoroughly rinse off the conditioner using water spray. - Dry with water- and oil-free air. - The etched enamel should have a mat white appearance; avoid contamination of the etched surface with saliva. In case of contamination, the conditioning must be repeated. - Application of Helioseal F Plus - Apply Helioseal F Plus directly with the singleuse cannula or the cavifil to the tooth surface, and disperse. - Cure the sealant using a suitable curing light. For detailed information on the exposure time see Table 1: **Light Intensity** / **Exposure time** ≥ 500 mW/cm² / 20s ≥ 1000 mW/ cm² / 10s - Check the seal and occlusion The accessories mentioned in the IFU (Proxyt, OptraDam Plus) do not require a 510(k).
Summary Principles of operation	There are minor differences in the wording for the application between Helioseal F and the new product Helioseal F Plus but these are not significant and the principle of operation is substantially equivalent.	

Summary of Chemical Composition	This chemical composition of the new device has slightly changed compared to the predicate. Both products are fissure sealants. Helioseal F Plus has proven biocompatibility and has been tested and evaluated according to ISO 6874:2015.	
Finished Device Specification	EN ISO 6874:2015 – Dentistry – Polymer-based pit and fissure sealants Applicable FDA Guidance: No information	EN ISO 6874:2015 – Dentistry – Polymer-based pit and fissure sealants Applicable FDA Guidance: Dental Composite Resin Devices – Premarket Notification [510(k)] Submission
Summary of Finished Device Specification	Helioseal F Plus fulfils the relevant product standard and follows the relevant FDA Guidance.	
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.
Single use	Consumable material	Consumable material
Summary of Performance Specification	No difference.	

Substantial Equivalence to the predicate:
Helioseal F Plus is a white-shaded fissure sealant featuring fluoride release like the predicate device Helioseal F. The indications, contraindications, technology, working principle and physical properties are the same. The chemical composition is comparable with regard to biocompatibility. Therefore, Helioseal F Plus is substantially equivalent to the predicate device, Helioseal F.

Differences:
The chemical composition of Helioseal F Plus has changed slightly compared to the predicate. Additionally, the shelf life of the new product Helioseal F Plus is 2 years compared to 2.5 years for the predicate Helioseal F.

Non-clinical performance testing:
Bench testing was performed to test the physical properties included in the Finished Device Specification for the subject device including: flexural strength, curing depth, light intensity, wavelength for curing, water sorption and water solubility and radio-Opacity according to FDA Guidance for Dental Composite Resin Devices and EN ISO 6874:2015- Dentistry- Polymer-based pit and fissure sealants. The subject device was tested in direct comparison to the predicate device and the results of the bench testing show the products to be substantially equivalent.

Biocompatibility:
The subject device was also evaluated for Biocompatibility according to ISO 10993-1:2009, ISO 7405:2008 and ISO 14971:2012. The following testing was conducted on the subject device: Cytotoxicity according to EN ISO 7405:2008 + A1:2013; ISO 10993-5:2009 and Genotoxicity according to EN ISO10993-3:2014 and the device was found to be non-cytotoxic and non-genotoxic. In addition to testing, additional criteria for biocompatibility including irritation, delayed-type hypersensitivity/Sensitization and systemic toxicity were also evaluated based on a review of the literature and the evaluation concluded the benefits provided by the subject device will exceed any potential biocompatibility risks. The Subject device was not tested or evaluated for implantation, pulp and dentine usage, pulp capping, endodontic usage, biodegradation, EMC, Software, animal and sterility validation as they are not applicable. The results of the Biocompatibility Assessment for Helioseal F Plus is substantially equivalent to the results of the Biocompatibility Assessment for the predicate device Helioseal F.

Conclusion:
Helioseal F Plus is a white-shaded fissure sealant featuring fluoride release like the predicate device Helioseal F. The indications, contraindications, technology, working principle and physical properties are the same. The chemical composition is comparable with regard to biocompatibility.

Therefore, Helioseal F Plus is substantially equivalent to the predicate device, Helioseal F.