February 11, 2020

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

Re: K191453
Trade/Device Name: Cervitec F
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: January 10, 2020
Received: January 14, 2020

Dear Ms. 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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*
K191453

Device Name
Cervitec® F

Indications for Use *(Describe)*

For treatment of dentinal hypersensitivity secondary to exposed dentin and root cervical surfaces.

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

K191453

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Date Prepared: February 10, 2020

Proprietary Name: **Cervitec® F**

Classification Name: Dental, Varnish, Cavity (872.3260)
(Classification Code LBH)

Device Class and panel: Class 2- dental

Primary Predicate: Fluor Protector S (K131487) by Ivoclar Vivadent, AG

Reference Device: Cervitec Plus (K072338) by Ivoclar Vivadent, AG

Reference Device: Biotene Mouthspray (K103745) by GlaxoSmithKline Consumer Healthcare

Device Description: **Cervitec® F** is a dental varnish for the treatment of dentinal hypersensitivity secondary to exposed dentin and root cervical surfaces. The varnish system is characterized by its good moisture tolerance during application. Cervitec F is supplied in either a Tube (4gm, 7gm) or Single Dose (0.26gm) delivery form.

Intended Use:

Cervitec F is applied by the dentist, dental hygienists, dental prophylaxis assistants or professionally instructed personnel. Cervitec F is suitable for all age groups.

Indications for Use:

For treatment of dentinal hypersensitivity secondary to exposed dentin and root cervical surfaces.

Comparison to Predicate:

The primary predicate devices to which Cervitec® F has been compared is Ivoclar Vivadent's Fluor Protector S (K131487)

Substantial Equivalence to the predicate and reference devices:

Device	Primary Predicate Device: Fluor Protector S (K131487)	Reference Device: Cervitec Plus (K072338)	Reference Device: Biotene Mouthspray (K103745)	Subject Device: Cervitec® F (K191453)
Manufacturer	**Ivoclar Vivadent AG**	**Ivoclar Vivadent AG**	**Glaxosmithkline Consumer Healthcare**	**Ivoclar Vivadent AG**
Indications for Use	Fluor Protector S is a protective fluoride varnish for tooth desensitization. – Treatment of dentinal hypersensitivity – Treatment of exposed cervicals – Treatment of sensitivity after tooth whitening	Cervitec Plus is a dental varnish material that is used for the protection of exposed root surfaces and treatment of hypersensitive cervicals	Relieves the symptoms of dry mouth; refreshes, moisturizes, sooths oral irritation, and lubricates oral dryness.	For treatment of dentinal hypersensitivity secondary to exposed dentin and root cervical surfaces.
Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	Contraindication If patients are known to be allergic to any of the ingredients of Fluor Protector S, the material should not be used. Application Fluor Protector S is applied by dentists and dental professionals. Fluor Protector S is suitable for treating patients of all ages. Side effects A slight temporary burning sensation may occur if the product comes in contact with the mucous membrane.	Contraindication If patients are known to be allergic to any of the ingredients in Cervitec Plus, the material should not be applied. Application Cervitec Plus can be used for patients of all age groups and is professionally applied by dentists, dental hygienists or dental prophylaxis assistants. Generally, Cervitec Plus is applied every three months. If intensive treatment is required, however, the varnish may also be applied more frequently. One Free Stand Single Dose Cervitec Plus is enough for the treatment of one set of teeth. One tube is enough for about 20-30 sets of teeth.	No information available	Contraindication If users are known to be allergic to any of the ingredients in Cervitec F, the material should not be applied. Application Cervitec F is applied by the dentist, dental hygienists, dental prophylaxis assistants or professionally instructed personnel. Cervitec F is suitable for all age groups. Side effects Contact with the mucous membrane may result in short term, reversible irritation. Chlorhexidine may cause reversible discoloration of the tooth structure and restorations. In rare, isolated cases, chlorhexidine may cause allergic reactions.

		Warning In rare, isolated cases, chlorhexidine may cause allergic reactions. Side effects In individual cases, contact with the mucous membrane may result in short-term, reversible irritation. Chlorhexidine may cause reversible discoloration of the tooth structure and restorations.		
Summary of Indications, Precaution Measures/ Contraindications/ Processing restrictions/ Side effects	The indications for the subject device are the same as for the predicate Fluor Protector S (the predicate has an additional one). Contraindications, application and side effects for both products are basically the same – there is a slight difference in the wording. The note for Chlorhexidine (side effect) is new – the predicate did not contain this component.			
Technology	Fluor Protector S is a protective varnish containing fluoride. Its purpose is the treatment of dentinal hypersensitivity, exposed cervicals and sensitivity after tooth whitening. Ethanol and water are the organic solvents. Fluoride ions lead to precipitation of calcium fluoride; this is an additional mechanism, which provides blockage and protection of exposed dentin tubules.	Cervitec Plus is a varnish that protects sensitive dentin in the case of exposed cervicals. Chlorhexidine and thymol are the antimicrobial components in Cervitec Plus. They protect the tooth surface by reducing bacterial activity.	Biotene Moisturizing Mouth Spray for Dry Mouth Symptom Relief is a specially formulated artificial saliva substitute, which contains moisturizers, humectants, a protein, and a patented salivary enzymes that collectively have lubricating, moisturizing, soothing, and refreshing properties to relieve & treat the symptoms of dry mouth.	Cervitec F contains fluoride in a varnish base. The varnish contains chlorhexidine and cetylpyridinium chloride and has a good moisture tolerance during application. Ethanol and water are the organic solvents. Fluoride ions lead to precipitation of calcium fluoride; this is an additional mechanism, which provides blockage and protection of exposed dentin tubules.
Summary of Technology	Even though the chemical composition is slightly different in both the predicate and subject device varnishes, the result is a thin, transparent layer-providing blockage of the dentinal tubules, the main working principle of the product.			
Delivery forms/dosage	Tube of liquid 4g Tube of liquid 7g Single dose 0.26g	Single dose Multi dose	1.5 oz non-pressurized pump action spray bottle fitted with cap	Tube of liquid 4g Tube of liquid 7g Single dose 0.26g
Summary of Delivery forms/dosage	No difference between the predicate and proposed devices.			

Storage Conditions	36 months at 2-28 °C / 36-82 °F	2-8 °C	No information available	36 months at 2-28 °C / 36-82 °F
Summary of Storage Conditions	The shelf life and the storage conditions are the same as for the predicate device Fluor Protector S.			
Principles of Operation	Step-by-step: - Clean the tooth surfaces. - Create a dry working field with cotton rolls, cotton wool wads and a saliva ejector or air syringe if necessary. - a) Single dose units: Peel the foil top from the single dose unit; apply the varnish directly from the single dose unit. - b) Dispensing tube: Place the required amount in a dappen dish or similar vessel and close the tube. - Apply a thin layer with the help of a Vivabrush G. - Let the varnish dry for one minute; thereafter, remove the cotton rolls. - After the treatment, ask the patient to spit out the contents of the mouth without rinsing. Tips for patients: patients should refrain from eating and drinking for one hour after the treatment with Fluor Protector S.	Step-by-step: 1. Clean tooth surfaces thoroughly. 2. Dry with cotton rolls and air syringe. 3. a) Single Dose: Remove the foil from the Single Dose and apply the varnish directly from the Single Dose. b) Tube: Press out 3 drops into, for example, a dappen dish and reseal the tube. Hold the tube in a vertical position with the cap facing upwards for opening and closing. For pressing out the contents, hold the opening vertically down. 4. Apply a thin coat of varnish by means of a Vivadent applicator or suitable brush (diagram); in proximal areas, Cervitec Plus is applied with dental floss. 5. Let the varnish dry. The varnish can be dispersed with air. 6. Remove cotton rolls after 30 seconds. 7. Ask patients not to rinse their mouth.	Method of Use: Ready to use spray Applications per Day: As needed	Step-by-step: - Clean the tooth surfaces. - Isolate the application area with cotton rolls and cotton swabs. - The use of a saliva ejector or air syringe is optional. - a) Single Dose unit: Remove the foil from the Single Dose and apply the varnish directly from the Single Dose. - b) Dosing tube: Dispense the required amount into e.g. a dappen dish and close the tube again. - Apply the varnish in a thin layer using e.g. Vivabrush G. - Allow the varnish to dry for 1 minute and then remove the cotton rolls. - No rinsing after application, only spitting. Eating and drinking should be avoided for 1 hour after application of Cervitec F. Vivabrush G is a class I medical device – therefore no 510(k) required
Summary Principles of operation	There are slight differences in the wording between the predicate and proposed device for the application, but the steps are basically the same.			
Composition	Acrylate copolymer	VA/Crotonates Copolymer and Chlorhexidine diacetate (CHX)	Cetylpyridinium chloride (CPC)	VA/Crotonates Copolymer, Chlorhexidine diacetate (CHX) and Cetylpyridinium chloride (CPC)
Summary Chemical Composition	The chemical composition slightly differs between the two devices to meet customer needs (improved moisture tolerance). The subject device formulation has been thoroughly assessed for biocompatibility and the result of the Biocompatibility Assessment of Cervitec F is substantially equivalent to the results for the predicate device. See attached Biocompatibility Assessment.			

Finished Device Specification	Applicable standard: ISO 17730:2014- Dentistry – Fluoride varnishes	No information available	No information available	Applicable standard: ISO 17730:2014- Dentistry – Fluoride varnishes
Sterilization	Not applicable. No sterilization recommendation.	Not applicable. No sterilization recommendation.	Non-sterile	Not applicable. No sterilization recommendation.
Single use	Consumable material	Single use only	No information available	Consumable material
Summary of Finished Device Specification	According to EN ISO 17730:2014 "Dentistry – fluoride varnishes" apart from the total fluoride content (the total fluoride content shall not deviate by more than 20% from the stated amount on the package), no other properties appear as being relevant for having the device functioning or performing as intended. Specific physical properties have been assessed and verified according to product standard EN ISO 17730:2014 – Dentistry- fluoride varnishes". The acceptance criteria of EN ISO 17730:2014 (the total fluoride content shall not deviate by more than 20% from the stated amount on the package) was fulfilled.			
Summary of Performance Specification	The performance is limited to the mechanical protection of hyper-sensitive teeth and exposed cervicals.			

Differences:

The chemical composition slightly differs between the predicate device and Cervitec F to meet customer needs (improved moisture tolerance). The differences between the submission device and the predicates do not raise concerns of safety and effectiveness for the submission device in comparison to the predicate devices.

Substantial Equivalence to the predicate and reference devices conclusion:

Both devices, the predicate device Fluor Protector S and the subject device Cervitec F are indicated for the protection of tooth structure by forming a protective varnish layer. In both cases, fluoride, a common agent in dental care products, enhances the mechanical protective effect.

Although the chemical formulation of Cervitec F is slightly different to the predicate device, the performance, function and biocompatibility remain the same. The biocompatibility of the subject device formulation was assessed and is equivalent to Fluor Protector S. The storage stability of the subject device formulation was assessed and is equivalent to Fluor Protector S. Therefore, Cervitec F is substantially equivalent to the predicate device, Fluor Protector S.

The reference devices were selected based on the chemical compositions; although slightly different, they do contain some of the same ingredients. This information is helpful in demonstrating substantial equivalence of the proposed device to its predicate.

Cervitec F contains VA/Crotonates Copolymer and Chlorhexidine diacetate (CHX), which are also included in Ivoclar Vivadent's Cervitec Plus cleared in 510(k) K072338 (reference device).

According to the appropriate Safety Data Sheet, Cetylpyridinium chloride (CPC) is also included in the following product of GlaxoSmithKline: the reference device Biotene Mouthspray cleared in 510(k): K103745 (Safety Data Sheet attached). Cetylpyridinium chloride (CPC) is used in Cervitec F.

Additionally, the components Alcohol, Aqua, Ammonium Fluoride, Peppermint aroma and Saccharin are found in the predicate device Fluor Protector S and in the proposed device Cervitec F.

Non-clinical performance testing:

According to EN ISO 17730:2014 "Dentistry – fluoride varnishes" apart from the total content (the total fluoride content shall not deviate by more than 20% from the stated amount on the package), no other properties appear as being relevant for having the device functioning or performing as intended. The Finished Device Specification confirms the product complies with the requirements as defined by ISO 17730:2014.

Biocompatibility:

Biocompatibility has been assessed according EN ISO 10993-1:2009 and EN ISO 7405:2008 and resulted in the following conclusions:
- Cervitec F is neither cytotoxic nor of acute or subchronic systemic toxicity.
- Cervitec F is not genotoxic
- Cervitec F does not induce oral mucosal irritation
- Cervitec F has a low sensitization potential

Based on the toxicological evaluation of the product, clinical studies of the product, research literature supporting the biocompatibility of Cervitec F and the longstanding worldwide clinical use of similar materials, it can be concluded that the benefits provided by the final product exceed any potential risks produced by constituent device materials, providing that the instructions for use have been followed. This supports the biocompatibility of the predicate device.

The subject device was not tested or evaluated for EMC, Software, animal and sterility validation as they are not applicable.

Conclusion:

The data show that Cervitec® F is substantially equivalent to the primary predicate device, Fluor Protector S (K131487) .