August 26, 2019

Dentsply Sirona
Karl Nittinger
Director, Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K191427
Trade/Device Name: Halley Resin System
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI, KLE, EBD
Dated: May 23, 2019
Received: May 29, 2019

Dear Karl Nittinger:

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)*
K191427

Device Name
Halley resin system

Indications for Use *(Describe)*
Halley resin is a light-cured resin indicated for the fabrication of dentures bases in dental laboratories, including full and partial dentures as well as implant overdentures, and other dental appliances. Halley resin can be used as a try-in material for evaluation prior to fabrication of the final restoration. Fabrication of these prostheses require a computer-aided design and manufacturing (CAD/CAM) system using an additive printer.

Halley resin can be utilized as an aid in bonding denture base to denture teeth as well as repair using traditional techniques.

Halley Denture-Tooth Bonding Agent is indicated for use in enhancing the bond of denture base to denture base.

Halley Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.

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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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

K191427

SECTION 5. 510(k) SUMMARY
for
Halley resin system

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: May 23, 2019

2. Device Name:
   - Proprietary Name: Halley resin system
   - Classification Name: Resin, Denture, Relining, Repairing, Rebasing
   - CFR Number: 21 C.F.R. 872.3760
   - Device Class: II
   - Product Code: EBI

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
Halley resin	K190043	Dentsply Prosthetics

Reference Device:

Reference Device Name	510(k)	Company Name
Eclipse® Bonding Agent	K051707	Dentsply Prosthetics
TEMPFX Esthetic Provisional System	K061264	Dentsply Prosthetics

4. Description of Device:
The proposed device, Halley resin system introduces two additional components (Halley Denture-Tooth Bonding Agent and Halley Sealer) to the Halley resin (K190043) workflow. The proposed Halley resin system consists of light-cured resins that support the modification of the Halley resin (K190043) workflow to include bonding and sealing steps using conventional techniques. The two additional components of the Halley resin system have previously been cleared under Eclipse® Bonding Agent, K051707 and TEMPFX Esthetic Provisional System, K061264. For comparison purposes, the reference device VLC Sealer (part of the TEMPFX Esthetic Provisional System, K061264) is being included. These devices are being included as reference devices (Eclipse® Bonding Agent, K051707 and TEMPFX Esthetic Provisional System, K061264) to support chemical composition and characteristics to support the Halley resin (K190043) workflow.

5. Indications for Use:
Halley resin (K190043) indications will be modified as follows (language to be added to the modified indications for use is identified in bold font):

Halley resin is a light-cured resin indicated for the fabrication of dentures bases in dental laboratories, including full and partial dentures as well as implant overdentures, and other dental appliances. Halley resin can be used as a try-in material for evaluation prior to fabrication of the final restoration. Fabrication of these prostheses require a computer-aided design and manufacturing (CAD/CAM) system using an additive printer.

Halley resin can be utilized as an aid in bonding denture base to denture teeth as well as repair using traditional techniques.

Halley Denture-Tooth Bonding Agent is indicated for use in enhancing the bond of denture base to denture base.

Halley Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.

6. Substantial Equivalence:
For the purpose of substantial equivalence, the proposed device, Halley resin system is compared to the legally marketed predicate device Halley resin (K190043) manufactured by Dentsply Prosthetics. The predicate device, Halley resin received U.S. premarket clearance in April 2019 under premarket notification K190043.

The proposed Halley resin system introduces two additional components to the Halley resin (K190043) workflow. In addition to the primary predicate device, Eclipse® Bonding Agent, K051707 and TEMPFX Esthetic Provisional System, K061264 are included to support substantial equivalence based on similarities in composition and characteristics to the proposed device.

The predicate device Halley resin (K190043) has been tested in accordance with ISO 20795-1:2013 - Dentistry – Base polymers – Part 1: Denture base polymers. The proposed Halley resin system and reference devices (Eclipse® Bonding Agent, K051707 and TEMPFX Esthetic Provisional System, K061264) have been tested to support the performance characteristics contributing to the Halley resin (K190043) workflow.

Table 5.1. details similarities and differences between the proposed, predicate and reference devices

Table 5.1	Proposed Device	Predicate Device	Reference Device	Reference Device	Similarities and Differences
Element	**Halley resin system**	**Halley resin**	**Eclipse® Bonding Agent**	**TEMPFX Esthetic Provisional System**	
510(k)	To be assigned	K190043	K051707	K061264	N/A
Indications for use	Halley resin is a light-cured resin indicated for the fabrication of dentures bases in dental laboratories, including full and partial dentures as well as implant overdentures, and other dental appliances. Halley resin can be used as a try-in material for evaluation prior to fabrication of the final restoration. Fabrication of these prostheses require a computer-aided design and manufacturing (CAD/CAM) system using an additive printer. Halley resin can be utilized as an aid in bonding denture base to denture teeth as well as repair using traditional techniques. Halley Denture-Tooth Bonding Agent is indicated for use in enhancing the bond of denture base to denture base. Halley Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.	Halley resin is a light-cured resin indicated for the fabrication of dentures bases in dental laboratories, including full and partial dentures as well as implant overdentures, and other dental appliances. Halley resin can be used as a try-in material for evaluation prior to fabrication of the final restoration. Fabrication of these prostheses require a computer-aided design and manufacturing (CAD/CAM) system using an additive printer. Halley resin can be utilized as an aid in bonding denture base to denture teeth as well as repair using traditional techniques.	Eclipse® Bonding Agent is indicated for use in enhancing the bond of acrylic teeth to acrylic removable denture bases.	TEMPFX Esthetic Provisional System is indicated for fabrication of provisional dental restorations.	-The proposed Halley resin system is a modification of the workflow cleared under the predicate device, Halley resin (K190043). Two additional components are introduced the Halley resin (K190043) workflow. -Additional components proposed for the Halley resin system have been previously cleared, Eclipse® Bonding Agent (K051707) and as part of TEMPFX Esthetic Provisional System (K061264) and are listed as reference devices. -Two additional components test reports support modifications to the Halley resin (K190043) workflow to include a bonding agent and sealer. -Both reference devices are currently utilized for similar uses in different workflows under K051707 and K061264. VLC Sealer is included within the system components as a light-curable resin material which forms a glossy surface. The identical VLC Sealer has been re-branded as Halley Sealer to support similar use for Halley resin system workflow.

Table 5.1 Element	Proposed Device Halley resin system	Predicate Device Halley resin	Reference Device Eclipse® Bonding Agent	Reference Device TEMPFX Esthetic Provisional System	Similarities and Differences
Composition	**Halley resin:** Methacrylate (mono and dimethacrylate) resins polymerized via photoinitiators Pigments are added for color of the denture. **Halley Denture-Tooth Bonding Agent:** Solvent vehicle containing Methacrylate (mono and dimethacrylate) resins polymerized via photoinitiators **Halley Sealer:** Methacrylate (mono and dimethacrylate) resins polymerized via photoinitiators	Methacrylate (mono and dimethacrylate) resins polymerized via photoinitiators in a 3D printer settings. Pigments are added for color of the denture.	Solvent vehicle containing Methacrylate (mono and dimethacrylate) resins polymerized via photoinitiators	Methacrylate (mono and dimethacrylate) resins polymerized via photoinitiators	-Composition of the proposed, predicate and reference device VLC Sealer (K061264) are similar. All devices are resins polymerized via photoinitiators. -No pigments are added to the proposed and reference devices. Additional color variations are not required for these devices. -The reference device, Eclipse Bonding Agent (K051707) uses a different solvent vehicle, however, after polymerization, the device composition is similar to the proposed, predicate devices. -The predicate device, Halley resin utilizes 3D printing workflow for device fabrication. The proposed and reference devices support the device fabrication workflow.
Application	Light-cured resin	Light-cured resin	Light-cured resin	Light-cured resin	-All devices are light-cured resins.
Use	Fabricated by Dental professionals in a dental laboratory	Fabricated by Dental professionals in a dental laboratory	Fabricated by Dental professionals in a dental laboratory	Fabricated by Dental professionals in a dental laboratory	-All devices are marketed and fabricated or printed by dental laboratories.

Table 5.1 Element	Proposed Device Halley resin system	Predicate Device Halley resin	Reference Device Eclipse® Bonding Agent	Reference Device TEMPFX Esthetic Provisional System	Similarities and Differences
Physical properties	No ISO standard available for these components; a combination of ISO 20795-1:2013, ISO 10477:2018 and internal requirements were tested to confirm performance.	ISO 20795-1:2013 (Dentistry – Denture base polymers) Type 4	No ISO standard available for these components; a combination of ISO 20795-1:2013, ISO 10477:2018 and internal requirements were tested to confirm performance.	No ISO standard available for these components; a combination of ISO 20795-1:2013, ISO 10477:2018 and internal requirements were tested to confirm performance.	-The predicate device Halley resin (K190043) complies with ISO 20795-1 for Type 4 materials. -The proposed Halley resin system and reference devices are minor parts of the restorations and do not have a unique standard requirement. -A combination of ISO standards and internal requirements were considered to support use as bonding agent and sealer. -Performance is based on testing.
Shelf life	3 years	3 years	Not submitted in the reference device 510(k)	Not submitted in the reference device 510(k)	Shelf life of the proposed device Halley resin system is based on performance testing.

7. Non-Clinical Performance Data

Physical Properties:

There are no specific ISO standards for supporting materials such as a bonding agent or a sealer. Performance of these proposed devices are linked to the Halley resin (K190043) workflow. These components are minor part of the overall device and the performance testing is limited to support its characteristic as a bonding agent or a sealer. These components were added and tested to align with predicate device, Halley resin (K190043).

Data derived from testing supports conclusion that the proposed device Halley resin system support the predicate device Halley resin (K190043) workflow.

Biocompatibility:

The predicate device, Halley resin (K190043) biocompatibility and test rationale remains unchanged from the current clearance. The patient contacting level and duration of the proposed Halley Denture-Tooth Bonding Agent and Halley Sealer are identical in material formulation and produced by the identical manufacturing methods as the reference devices. Therefore, no new biocompatibility testing was conducted for the proposed Halley resin system.

8. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the proposed device, Halley resin system.

9. Conclusion Regarding Substantial Equivalence

The proposed device, Halley resin system testing supports the cleared predicate device, Halley resin (K190043) workflow for the following reasons:

- Both components were tested to support the modification of the cleared predicate device, Halley resin (K190043) and its workflow.
- Both components have been previously cleared for similar use and the material composition is identical to the cleared reference devices, Eclipse® Bonding Agent, K051707 and TEMPFX Esthetic Provisional System, K061264.
- The test data to verify the performance and biological safety of the proposed device, Halley resin system, has been provided. The results of this testing combined with the characteristics supporting the modified workflow support substantial equivalence.