April 24, 2019

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

Re: K190043
Trade/Device Name: Halley Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: January 24, 2019
Received: January 25, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K190043

Device Name
Halley resin

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.

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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K190043

SECTION 5. 510(k) SUMMARY
for
Halley resin

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: 08 January 2019

2. Device Name:

- Proprietary Name: Halley resin
- 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
NextDent™ Denture / E-Denture	K162572	Vertex-Dental BV

Reference Device:

Reference Device Name	510(k)	Company Name
Pour Acrylic	K161330	Dentsply Prosthetics

4. Description of Device:

The proposed Halley resin is a methacrylate-based, light-cured resin available in multiple shades and is intended as an alternative to traditional heat cured and auto-polymerization denture base resins. The Halley resin is intended to be utilized primarily for the fabrication of dental prostheses using an additive printer and CAD/CAM techniques. The proposed Halley resin can also be used for traditional repairs and as an aid in bonding denture base to denture teeth.

In addition, Halley resin may also be utilized as an aid in bonding the printed denture to teeth as well as for repair.

5. 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.

6. Substantial Equivalence:

Technological Characteristics:

For the purpose of substantial equivalence, the proposed Halley resin is compared to the predicate device, NextDent™ Denture / E-Denture (K162572). The predicate device, NextDent™ Denture / E-Denture (K162572) is being compared to the proposed device Halley resin to establish substantial equivalence to the proposed device Halley resin, specifically for performance and processing similarities related to 3D additive printing.

In addition to the primary predicate device, Pour Acrylic (K161330) is included as a reference device in support of substantial equivalence. The reason for inclusion of the reference device, Pour Acrylic (K161330), is to support similarities in technological properties and performance characteristics to the proposed device.

The proposed, predicate, and reference devices have been tested according to the requirements of ISO 20795-1:2013 (*Dentistry — Base polymers — Part 1: Denture base polymers*) as Type 2 or 4 materials. Table 5.1 compares the proposed device, Halley resin, the predicate device, NextDent™ Denture / E-Denture (K162572), and the reference device, Pour Acrylic (K161330).

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

Element	Proposed Device Halley resin	Predicate Device NextDent™ Denture/E-Denture	Reference Device Pour Acrylic	Similarities and Differences
510(k)	To be assigned	K162572	K161330	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.	NextDent™ Denture / E-Denture is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. NextDent™ Denture / E-Denture is intended exclusively for professional dental work. Fabrication of denture bases with NextDent™ Denture / E-Denture require a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer and post-cure unit. NextDent™ Denture / E-Denture is compatible with the following CAD/CAM systems components: Design: Brand: 3Shape; Type: D900 Scanner: 3Shape Design Software: Dental-System 2016-Premium Printing: Brand: Envisiontec; Type: DDDP 4; Software: Perfactory Printer: Rapidshape; Type: D30; Software: NetFabb Miicraft; 125Y; MiiUtility MiiController 3D systems; Figure 4; 3D Sprint Ver1.1 Roland DG; DWP-80S Post-Curing: Brand: NextDent™; Type: LC-3D PrintBox Post-Cure unit	Pour Acrylic resin is a self-curing denture base material designed for use in fabrication, repair, rebasing, or relining of full and partial dentures including implant overdentures or other dental appliances.	• Both the proposed device, Halley resin, and the predicate device, NextDent™ Denture / E-Denture (K162572), are light-cured resins that utilize CAD/CAM techniques to print devices. • The proposed Halley resin is also indicated for use as an aid in bonding as well as repair using traditional techniques. These are common uses for denture materials where the same materials are used for bonding and repair. Similarly, the reference device Pour Acrylic (K161330) is also indicated for repair using traditional techniques. • The proposed Halley resin is also intended for use as a try-in material for fit evaluation. • Additionally, the proposed Halley resin is also indicated for implant overdenture and dental appliances; these additional terms are cleared for the reference device Pour Acrylic (K161330), a Type 2 material per ISO 20795-1 standard. The proposed Halley resin (a Type 4 material per ISO 20795-1 standard) meets more stringent requirements than the reference device. The proposed device Halley resin is supported by performance characteristics to meet its intended use.

Table 5.1 Similarities and differences between the proposed, predicate and reference devices.				
Element	**Proposed Device Halley resin**	**Predicate Device NextDent™ Denture/E-Denture**	**Reference Device Pour Acrylic**	**Similarities and Differences**
CFR Section	872.3760, FDA product code: EBI	872.3760, FDA product code: EBI	872.3760, FDA product code: EBI	All devices are classified under the same regulation.
Composition	Methacrylate resins (mono and dimethacrylate) polymerized via photoinitiators in a 3D printer settings. Pigments are added for color of the denture.	Dimethacrylate resins polymerized via photoinitiators in a 3D printer settings. Pigments are added for color of the denture.	polymethylmethacrylate-based resins materials with initiator, inhibitor and pigments	Both the predicate device, NextDent™ Denture / E-Denture (K162572), and the proposed device, Halley resin, have comparable generic composition description. Though the exact composition of the predicate device is not known; extensive biocompatibility studies have been conducted to verify the biological safety of the proposed device Halley resin in support of substantial equivalence.
Application	Light-cured resin Automated 3D printing of resin in multiple layers, each light-cured before printing of next layer, with post curing in a light curing unit	Light-cured resin Automated 3D printing of resin in multiple layers, each light-cured before printing of next layer, with post curing in a light curing unit	Self-cured resin Manual application, self-polymerizing material, with post curing in a curing unit.	• Both the predicate device, NextDent™ Denture / E-Denture (K162572), and the proposed device, Halley resin, are light-cured resins that utilize automated 3D printing technology to print dental devices layer by layer. • The reference device, Pour Acrylic (K161330), utilizes self-curing or auto-polymerizing techniques to cure the dental device.
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	All devices are marketed and fabricated or printed by dental laboratories.

Table 5.1 Similarities and differences between the proposed, predicate and reference devices.				
Element	**Proposed Device Halley resin**	**Predicate Device NextDent™ Denture/E-Denture**	**Reference Device Pour Acrylic**	**Similarities and Differences**
Physical properties	ISO 20795-1:2013 (Dentistry – Denture base polymers) Type 4 Meets requirements of Type 2 materials	ISO 20795-1:2013 (Dentistry – Denture base polymers) Type 4 except Water Solubility which meets requirements of Type 2 materials for Water Solubility	ISO 20795-1:2013 (Dentistry – Denture base polymers) Type 2 Class 2	• All devices were tested in accordance with ISO 20795-1 standard. The proposed Halley resin met the requirements of a Type 4 and 2 materials. • The predicate device NextDent™ Denture / E-Denture (K162572) did not meet the requirements of Type 4 material for Water Solubility but meets a broader specification of Type 2 material. • The performance characteristics are comparable for the predicate device, NextDent™ Denture / E-Denture (K162572), reference device Pour Acrylic (K161330) and proposed device Halley resin.
Shelf life	3 years	2 years	3 years	Shelf life of the proposed device Halley resin is based on performance testing.

7. Non-Clinical Performance Data

Physical Properties:

Data derived from testing in accordance with ISO 20795-1:2013 (*Dentistry – Base polymers – Part 1: Denture base polymers*) is included to support substantial equivalence. The data support a conclusion that the proposed device Halley resin, predicate device NextDent™ Denture / E-Denture (K162572) and the reference device Pour Acrylic (K161330) are comparable and meet the requirements per ISO 20795-1 standard as shown in Table 5.2 below.

Table 5.2 Comparison of Performance Data/Physical Properties					
Physical Property	**Standard (ISO) ISO 20795-1 :2013 Specification Limit Type 4**	**Standard (ISO) ISO 20795-1 :2013 Specification Limit Type 2**	**Proposed Device Halley resin Type 4**	**Predicate Device NextDent™ Denture / E-Denture K162572* Type 4**	**Reference Device Pour Acrylic K161330** Type 2**
Ultimate Flexural Strength (MPa)	65 MPa min.	60 MPa min.	Meets ISO 20795-1:2013 for Type 4 material	Meets ISO 20795-1:2013 for Type 4 material* >65 MPa	Meets ISO 20795-1:2013 for Type 2 material**
Flexural Modulus (MPa)	2000 MPa min.	1500 MPa min.	Meets ISO 20795-1:2013 for Type 4 material	Meets ISO 20795-1:2013 for Type 4 material* >2000 MPa	Meets ISO 20795-1:2013 for Type 2 material**
Water Sorption ($\mu g/mm^3$)	32 $\mu g/mm^3$ max.	32 $\mu g/mm^3$ max.	Meets ISO 20795-1:2013 for Type 4 material	Meets ISO 20795-1:2013 for Type 4 material* ≤ 32 $\mu g/mm^3$	Meets ISO 20795-1:2013 for Type 2 material**
Water Solubility ($\mu g/mm^3$)	1.6 $\mu g/mm^3$ max.	8.0 $\mu g/mm^3$ max.	Meets ISO 20795-1:2013 for Type 4 material	Exceeds ISO 20795-1:2013 for Type 4 material (< 1.6 $\mu g/mm^3$) but meets specification for Type 2 material* ≤ 8.0 $\mu g/mm^3$	Meets ISO 20795-1:2013 for Type 2 material**
Residual methyl methacrylate monomer	2.2% max.	4.5% max.	Meets ISO 20795-1:2013 for Type 4 material	Meets ISO 20795-1:2013 for Type 4 material* ≤ 2.2%	Meets ISO 20795-1:2013 for Type 2 material**
UV Color Stability	The material show no more than a slight change in color (report as pass/fail)	The material show no more than a slight change in color (report as pass/fail)	Meets ISO 20795-1:2013 for Type 4 material	Not reported	Meets ISO 20795-1:2013 for Type 2 material**

Table 5.2 Comparison of Performance Data/Physical Properties					
Physical Property	**Standard (ISO) ISO 20795-1 :2013 Specification Limit Type 4**	**Standard (ISO) ISO 20795-1 :2013 Specification Limit Type 2**	**Proposed Device Halley resin Type 4**	**Predicate Device NextDent™ Denture / E-Denture K162572* Type 4**	**Reference Device Pour Acrylic K161330** Type 2**
Fracture Toughness – maximum stress intensity work, Kmax (MPa $m^{1/2}$)	1.9 MPa $m^{1/2}$ min.	1.9 MPa $m^{1/2}$ min.	Meets ISO 20795-1:2013 for Type 4 material	Not reported	Meets ISO 20795-1:2013 for Type 2 material**
Fracture Toughness – total fracture work, W_f (J/m^2)	900 J/m^2 min.	900 J/m^2 min.	Meets ISO 20795-1:2013 for Type 4 material	Not reported	Meets ISO 20795-1:2013 for Type 2 material**
*Data derived from predicate device K162572 510(k) Summary, Appendix A. **Reference device Pour Acrylic (K161330) data is available to Dentsply Sirona.					

Biocompatibility:

Biocompatibility testing was conducted for the proposed Halley resin to support device safety. The following standards were utilized to perform biocompatibility testing. In addition, Oral toxicity test was performed to support the proposed device Halley resin.

The results of the biocompatibility testing conducted on the proposed Halley resin support substantial equivalence.

- ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for* in vitro *cytotoxicity*
- ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ISO 10993-6, *Biological evaluation of medical devices – Part 6: Tests for local effects of implantation*
- ISO 10993-3, *Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity*

8. Clinical Performance Data

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

9. Conclusion Regarding Substantial Equivalence

The proposed device, 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.

The proposed device, Halley resin, has the same intended use, similar indications for use, and incorporates the same fundamental technology as the predicate device, NextDent™ Denture / E-Denture (K162572). The proposed device, Halley resin is also comparable to the reference device Pour Acrylic (K161330) for performance characteristics and meets a more stringent specification requirement of ISO 20795-1:2013 standard. Test data to verify the performance and biological safety of the proposed device, Halley resin, has been provided including physical properties in accordance with ISO 20795-1 and ISO 10993-1 standard. The results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.