October 20, 2023

Dentsply Sirona
Rebecca Sporer
Principle Regulatory Affairs Specialist
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K231578
Trade/Device Name: Lucitone Digital Print Denture System
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, KLE, PZY, EBD
Dated: May 31, 2023
Received: May 31, 2023

Dear Rebecca Sporer:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Bobak Shirmohammadi -S

Michael E. Adjodha, M. ChE., CQIA
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231578

Device Name

Lucitone Digital Print Denture System

Indications for Use *(Describe)*

• Lucitone Digital Print™ 3D Denture Base is a light-cured resin indicated for the fabrication of denture bases including full and partial dentures and implant overdentures, and implant overdentures and other dental appliances.
• Lucitone Digital Value™ 3D Economy Tooth & Trial Placement is used as a try-in material for evaluation prior to fabrication of the final restoration or a temporary denture.
• Lucitone Digital IPN™ 3D Premium Tooth is a light-cured resin intended for printing denture teeth.
• Lucitone Digital Value™ 3D Economy Tooth & Trial Placement is intended for printing full arch and tooth segments.
• Lucitone Digital Fuse™ Step 1 – 3D Tooth Conditioning Agent is indicated for use in enhancing the bond of denture teeth to denture base and denture base to denture base.
• Lucitone Digital Fuse™ Step 2 – 3D Denture Bonding Resin is utilized as an aid in bonding denture teeth to denture base as well as repair using traditional techniques.
• Lucitone Digital Fuse™ Step 3 – Total 3D 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

510(k) SUMMARY
for
Lucitone Digital Print Denture System (**K231578**)

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17404

Contact Person: Ms. Rebecca Sporer
Telephone Number: 717-353-1150
Email address: Corporate-RA@dentsplysirona.com

Date Prepared: 19 October 2023

2. Device Name:

Proprietary Name:	Lucitone Digital Print Denture System
Common Name:	Denture relining, repairing or rebasing resin
Classification Name:	Resin, Denture, Relining, Repairing, Rebasing
CFR Number:	21 CFR 872.3760
Device Class:	II
Product Code:	EBI, KLE, EBD, EBG

3. Predicate Device:

Table FS.1: Predicate and Reference device information

Device Type	Predicate Device Name	510(k)	Company Name
Primary Predicate Device	Halley Resin System	K191427	Dentsply Sirona
Predicate Device	Eclipse Bonding Agent	K051707	Dentsply Sirona
Reference Device	Halley Resin	K190043	Dentsply Sirona
Reference Device	TempFX Esthetic Provisional System	K061264	Dentsply Sirona

4. Description of Device:

Lucitone Digital Print Denture System is a methacrylate-based, light-cured denture base resin which is intended for use by dental clinician to fabricate dental prostheses using an additive printer and CAD/CAM technologies or as a try-in denture. The workflow utilizes several support components that aid in conditioning, bonding or sealing to provide a smooth finish to the device. The Lucitone Digital Print Denture System conforms to the physical and mechanical property requirements for ISO 20795-1:2013.

5. Indications for Use:

Indications for Use for the proposed device are:

- Lucitone Digital Print™ 3D Denture Base is a light-cured resin indicated for the fabrication of denture bases including full and partial dentures and implant overdentures, and implant overdentures and other dental appliances.
- Lucitone Digital Value™ 3D Economy Tooth & Trial Placement is used as a try-in material for evaluation prior to fabrication of the final restoration or a temporary denture.
- Lucitone Digital IPN™ 3D Premium Tooth is a light-cured resin intended for printing denture teeth.
- Lucitone Digital Value™ 3D Economy Tooth & Trial Placement is intended for printing full arch and tooth segments.
- Lucitone Digital Fuse™ Step 1 - 3D Tooth Conditioning Agent is indicated for use in enhancing the bond of denture teeth to denture base and denture base to denture base.
- Lucitone Digital Fuse™ Step 2 - 3D Denture Bonding Resin is utilized as an aid in bonding denture teeth to denture base as well as repair using traditional techniques.
- Lucitone Digital Fuse™ Step 3 - Total 3D Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.

Table FS.2 compares the proposed Indications for Use with those of the predicate and reference devices.

Table FS.2 - Indications for Use Side-by-Side Comparison					
Proposed Device Lucitone Digital Print Denture System (K231578)	**Primary Predicate Device Halley Resin System (K191427)**	**Reference Device Halley Resin (K190043)**	**Predicate Device Eclipse Bonding Agent (K051707)**	**Reference Device TempFX Esthetic Provisional System (K061264)**	**Differences**
• Lucitone Digital Print 3D Denture Base is a light-cured resin indicated for the fabrication of denture bases including full and partial dentures and implant overdentures and other dental appliances.	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.		N/A	N/A	Similar. -The proposed device indication does not state "in dental laboratories" as the proposed device is targeted for use by dental professionals in a dental laboratory or a clinical setting. -Product name "Lucitone Digital Print 3D Denture Base" instead of "Halley resin"
• Lucitone Digital IPN™ 3D Premium Tooth is a light-cured resin intended for printing denture teeth.			N/A	N/A	Different. Additional component in indication. -The additional indication for use falls under the scope of product code PZY (additively manufactured, preformed, resin denture tooth) which is 510(k) exempt device.
• Lucitone Digital Value 3D Economy Tooth & Trial Placement is used as a try-in material for evaluation prior to	Halley resin can be used as a try-in material for evaluation prior to fabrication of the final restoration.		N/A	N/A	Similar. -The proposed Try-in denture can also be used as a temporary denture. The extension of use is supported by physical and mechanical

Table FS.2 - Indications for Use Side-by-Side Comparison					
Proposed Device Lucitone Digital Print Denture System (K231578)	**Primary Predicate Device Halley Resin System (K191427)**	**Reference Device Halley Resin (K190043)**	**Predicate Device Eclipse Bonding Agent (K051707)**	**Reference Device TempFX Esthetic Provisional System (K061264)**	**Differences**
fabrication of the final restoration, or a temporary denture					properties per ISO 20795-1:2013 *Dentistry – Base polymers – Part 1: Denture base polymers*; -Product name "Lucitone Digital Value 3D Premium Tooth & Trial Placement" instead of "Halley resin"
• Lucitone Digital Value™ 3D Economy Tooth & Trial Placement is intended for printing full arch and tooth segments.			N/A	N/A	Different. Additional component in indication. -The additional indication for use falls under the scope of product code PZY (additively manufactured, preformed, resin denture tooth) which is 510(k) exempt device.
• Lucitone Digital Fuse Step 1- 3D Tooth Conditioning Agent is indicated for use in enhancing the bond of denture teeth to denture base and denture base to denture base.	Halley Denture Tooth Bonding Agent is indicated for the use in enhancing the bond of denture base to denture base.		Eclipse® Bonding Agent is indicated for use in enhancing the bond of acrylic teeth to acrylic removable denture base.	N/A	Similar. -Additional indication for use for bonding denture teeth to the denture base cleared in the predicate device (K051707) (identical formulation).

Table FS.2 - Indications for Use Side-by-Side Comparison					
Proposed Device Lucitone Digital Print Denture System (K231578)	**Primary Predicate Device Halley Resin System (K191427)**	**Reference Device Halley Resin (K190043)**	**Predicate Device Eclipse Bonding Agent (K051707)**	**Reference Device TempFX Esthetic Provisional System (K061264)**	**Differences**
					-Product name "Lucitone Digital Fuse Step 1 – 3D Tooth Conditioning Agent" instead of "Halley Denture Tooth Bonding Agent"
• Lucitone Digital Fuse Step 2- 3D Denture Bonding Resin in utilized as an aid in bonding denture teeth to denture base as well as repair using traditional techniques.	Halley resin can be utilized as an aid in bonding denture base to denture teeth as well as repair using traditional techniques.		N/A	N/A	Similar. -Reworded for clarification. -Product name "Lucitone Digital Fuse Step 2 – 3D Denture Bonding Resin" instead of "Halley resin"
• Lucitone Digital Fuse Step 3 – Total 3D Sealer is a light-cured sealant that produces a smooth, glossy surface finish on the denture.	Halley Sealer is light-cured sealant that produces a smooth, glossy surface finish on the denture.		N/A	TEMPFX ESTHETIC PROVISIONAL SYSTEM is indicated for fabrication of provisional dental restorations.	Same -Product name "Lucitone Digital Fuse Step 3 – Total 3D Sealer" instead of "Halley Sealer"

6. Comparison of Technological Characteristics:

The proposed Lucitone Digital Print Denture System includes the addition of the Primeprint 3D printer workflow. The workflow has been modified to include new packaging (cartridge), the use of a new washing agent, and minor modifications when compared to the primary predicate device workflow (Kl91427). The overall sequential workflow between the dentist (or dental professional) and the dental laboratory of the proposed Lucitone Digital Print Denture System is identical to the workflow of the primary predicate device Halley Resin System (Kl 91427). Although the packaging of the resin was modified, the formulation of the denture base resin and try-in denture resin remain the same as the predicate device (Kl91427). Both the proposed and predicate device have comparable percent extractables, which confirms the biological safety of the proposed device.

The proposed device was also modified to include cumulative changes made to the predicate device (Kl91427). There were minor formulation updates to ancillary components of the system in trace percentages. Biological safety testing was performed to confirm the biological safety of the proposed device in comparison with the predicate device.

7. Non-Clinical Performance Data

The proposed device was tested and conforms to ISO 20795-1:2013 Type 4 materials and follows FDA guidance documents:

1) Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration Staff (April 2022)
2) FDA Guidance Technical Considerations for Additive Manufactured Medical Devices (December 2017). The proposed device meets the same technological requirements as the predicate device (Kl 91427).

8. Clinical Performance Data

Not applicable, no data from human clinical studies has been included to support the substantial equivalence of the proposed Lucitone Digital Print Denture System.

9. Conclusion

Minor differences in the technological characteristics between the proposed and predicate (Kl 91427) device were evaluated through appropriate performance and biocompatibility testing which demonstrates that the proposed device, when compared to the predicate device,

does not raise new questions regarding safety and effectiveness. Therefore, nonclinical testing data supports the conclusion that the proposed device is substantially equivalent to the predicate device (Kl 91427).