December 17, 2024

Dentsply Sirona Inc.
Melanie Avila
Regulatory Affairs Director
221 West Philadelphia St.
Suite 60W
York, Pennsylvania 17401

Re: K243336
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, EBG
Dated: October 24, 2024
Received: October 24, 2024

Dear Melanie Avila:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243336

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.
• 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 use as:
• Printing resin for fabricating removable dentures for try-in and evaluation prior to fabrication of the final denture.*
• Printing resin for fabricating a temporary denture.
• Printing resin for fabricating denture teeth in full arches and segments that will subsequently be fused into a denture base.
• Printing resin for fabricating provisional crowns, bridges.**
• 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.

*Partial and full dentures are replacement for patients with missing teeth.†
**For instructions on printing provisional crowns and bridges with Lucitone Digital Value reference Section G in IFU
†Statement added for EU MDR alignment.

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.

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

K243336

510(k) SUMMARY

1. Submitter Information:

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

Contact Person: Melanie Avila
Telephone Number: 210-262-7724
Email address: melanie.avila@dentsplysirona.com

Date Prepared: October 22, 2024

2. Device Name:

Device Trade Name	Lucitone Digital Print™ Denture System
Common Name:	Denture Relining, Repairing, Or Rebasing Resin Temporary Crown and Bridge
Classification Name:	Resin, Denture, Relining, Repairing, Rebasing Temporary Crown and Bridge
Regulation Number	872.3760 872.3770
Device Class:	II
Product Code:	EBI, KLE, PZY, EBD, EBG

3. Predicate Device:

Primary Predicate Device	510(k)	Company Name
Lucitone Digital Print™ Denture System	K231578	Dentsply Sirona Inc

Secondary Predicate Device	510(k)	Company Name
Dentca Crown and Bridge	K192806	Dentca Inc

4. Description of Device:

Lucitone Digital Value™ (LDV) 3D Economy Tooth & Trial Placement, which is part of the Lucitone Digital Print™ Denture (LDPD) System, is a methacrylate-based resin system which is used to fabricate dental prostheses using an additive printer and computer aided design and computer aided manufacturing (CAD/CAM) technologies.

5. Indications for Use:

- 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.
- 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 use as:

- Printing resin for fabricating removable dentures for try-in and evaluation prior to fabrication of the final denture.*
- Printing resin for fabricating a temporary denture.
- Printing resin for fabricating denture teeth in full arches and segments that will subsequently be fused into a denture base.
- Printing resin for fabricating provisional crowns, bridges.**
- 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.

*Partial and full dentures are replacement for patients with missing teeth.†
**For instructions on printing provisional crowns and bridges with Lucitone Digital Value reference Section G in IFU
†Statement added for EU MDR alignment.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]			
Attribute	**Subject Device:** Lucitone Digital Print™ Denture System	**Predicate Device:** Lucitone Digital Print™ Denture System	**Predicate Device:** Dentca Crown and Bridge
Material	Methacrylate-based resin	Methacrylate-based resin	

Sterility	Non-Sterile	Non-Sterile	
Shelf Life	3 years	3 years	
Performance Testing			
Flexural Strength (MPa)	≥50 MPa.		≥50 MPa.
Flexural Modulus (MPa)	Acceptable		Acceptable
Water Sorption (µg/mm³)	<40 µg/mm^3		<40 µg/mm^3
Water Solubility (µg/mm³)	< 7.5 µg /mm^3		< 7.5 µg /mm^3
Biocompatibility	Meets ISO 10993 requirements	Meets ISO 10993 requirements	

Performance Data

Summary of non-clinical tests conducted for determination of substantial equivalence:

The subject device, LDV, which is part of the LDPD system (primary predicate, cleared under 510(k) K231578) is a resin-based system which is used to fabricate dental prostheses using an additive printer.

- Flexural Strength
- Flexural Modulus
- Water Sorption
- Water Solubility

In all instances, the subject device functioned as intended and all test results observed were as expected.
The testing generated strong evidence that the Lucitone Digital Print™ Denture System has been found to be safe and effective.

Clinical and Pre-clinical testing were not necessary to demonstrate equivalence.

Conclusions
The minor differences in indications for use do not raise any new questions of safety and efficacy and the performance data established by the predicate, including biocompatibility, shelf-life testing and bench testing demonstrate substantial equivalence to the predicate.
The subject device's fundamental technology and principles of operation are unchanged compared to the primary predicate device. The subject device's Intended Use remains the same as the predicate device as cleared under K231578.

The subject device is as safe and effective as the predicate devices.