November 17, 2022

Dentca, Inc.
Jason Lee
Principal Scientist
357 Van Ness Way, Ste 250
Torrance, California 90501

Re: K220042
Trade/Device Name: Dentca Base Premium, Dentca Base Hi-Impact
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: October 18, 2022
Received: October 19, 2022

Dear Jason Lee:

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,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
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.

510(k) Number *(if known)*
K220042

Device Name
DENTCA Base Resin

Indications for Use *(Describe)*
DENTCA Base Resin is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. DENTCA Base Resin can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures.
Fabrication of these prostheses with DENTCA Base Resin requires a digital denture file, additive printer, and curing light equipment.
DENTCA Base Resin can be utilized as an aid in bonding the denture teeth onto denture base.

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 - K220042

Submitter

DENTCA, INC.
357 Van Ness Way, Suite 250
Torrance, CA 90501

Phone: 424-558-8726
Fax: 424-558-8738
Contact Person: Jason Lee
Date Prepared: December 3, 2021
Date Revised: October 14, 2022

Device Classification

Proprietary Name:	DENTCA Base Resin
Trade Name:	DENTCA Base Premium, DENTCA Base Hi-Impact
Common Name:	Dental Acrylic Resin
Classification Name:	Denture relining, repairing, or rebasing resin
Regulation Number:	21 CFR 872.3760
Product Code:	EBI
Regulatory Class:	II
Review Panel:	Dental

Predicate Device

The following predicate is a legally marketed, post-amendment device:

510(k) Number:	K190043
Clearance Date:	April 24, 2019
Trade Name:	Halley Resin
Actual Trade Name:	Lucitone Digital Print
Manufacturer:	Dentsply Sirona
Regulation Number:	21 CFR 872.3760
Product Code:	EBI

Reference Device

The following reference is a legally marketed, post-amendment device:

510(k) Number:	K160244
Clearance Date:	March 3, 2017
Actual Trade Name:	DENTCA Denture Base II
Manufacturer:	DENTCA, Inc.
Regulation Number:	21 CFR 872.3760
Product Code:	EBI

Device Description

DENTCA Base Resin is a light-curable resin intended to fabricate removable dentures in a CAD/CAM system using an additive printing process. This material is used as an alternative to traditional heat cured and auto polymerizing denture base resins and is available in multiple shades. DENTCA Base Resin can also be utilized to repair the printed denture and to bond printed teeth onto denture base.

Indications For Use

DENTCA Base Resin is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. DENTCA Base Resin can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures. Fabrication of these prostheses with DENTCA Base Resin requires a digital denture file, additive printer, and curing light equipment.
DENTCA Base Resin can be utilized as an aid in bonding the denture teeth onto denture base.

Both the subject and predicate are light-curable resins indicated for fabrication and repair of dental prostheses.

Comparison of Technological Characteristics With Predicate

The following table compares technological and other characteristics of the subject, predicate, and reference devices.

Table 5.1 Comparison of Technical Features

	Subject Device	Predicate Device	Reference Device	Similarities and Differences
Device Names	**DENTCA Base Resin**	**Halley Resin**	**DENTCA Denture Base II**	**NA**
Regulation & Product Code	872.3760; EBI	872.3760; EBI	872.3760; EBI	Same Classification
Intended Use	Fabrication and repair of removable denture bases and dental appliances	Fabrication and repair of removable denture bases and dental appliances.	Fabrication and repair of removable denture bases and dental prosthesis	Same Intended Use
Indications For Use	DENTCA Base Resin is a light-curable resin indicated for the fabrication and repair of removable denture bases in dental laboratories, including full and partial dentures as well as immediate dentures, and baseplates. DENTCA Base Resin can also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures.	Halley resin is a light-cured resin indicated for the fabrication of denture 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	DENTCA Denture Base II is a light-curable resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-curable and auto polymerizing resins. Fabrication of dental prosthetics with DENTCA Denture Base II requires a computer-aided design and manufacturing	All three devices are light-cure resins indicated for fabrication and repair of dental prostheses.

	Fabrication of these prostheses with DENTCA Base Resin requires a digital denture file, additive printer, and curing light equipment. DENTCA Base Resin can be utilized as an aid in bonding the denture teeth onto denture base.	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.	(CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, stereolithographic additive printer, and curing light equipment.	

Device Description

Resin Type	Type 4, Light-cure resin	Type 4, Light-cure resin	Type 4, Light-cure resin	Same Technology
Chemical Composition	Acrylate-based resins with photoinitiator, and pigments	Acrylate-based resins with photoinitiator, and pigments	Acrylate-based resins with photoinitiator, and pigments	Same Technology
Fabrication Method of Denture Base	Automated 3D printing of resin in multiple layers, and post-curing in light curing unit	Automated 3D printing of resin in multiple layers, and post-curing in light curing unit	Automated 3D printing of resin in multiple layers, and post-curing in light curing unit	Same Technology
Teeth Assemble	Chemical Bonding	Chemical Bonding	Chemical Bonding	Same Technology
Requirement	Meets the specification of ISO 20795-1 for Type 4 material	Meets the specification of ISO 20795-1 for Type 4 material	Meets the specification of ISO 20795-1 for Type 4 material	Same Standard
Intended User	Fabricated by Dental professionals in a dental lab	Fabricated by Dental professionals in a dental lab	Fabricated by Dental professionals in a dental lab	Same User

The above comparison shows the similarities on indications for use and technological aspects among the devices. A comparison proved that all devices fabricate the denture bases and dental prosthesis in the same manner, via automated application of a light-cure resins in an additive 3D printer.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for DENTCA Base Resin was conducted in accordance with the standard ISO 7405:2018 *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry* and the FDA Guidance *"Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."*

The denture base is considered tissue contacting for a period longer than 30 days (a removable prosthesis).

Software Verification and Validation Testing

The operation software for additive printing (3D printer) was verified and validated in accordance with the FDA guidance *"FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices"* and "*Technical Considerations for Additive Manufactured Medical Devices.*"

Performance Bench Test

Bench test for DENTCA Base Resin was conducted in accordance with ISO 20795-1:2013, as recognized by FDA. The data support a conclusion that the subject device meets the requirements per ISO 207495-1 standard as presented in Table 5.2 below.

Table 5.2 Comparison of Performance Bench Test

Representative Physical Properties	ISO 20795-1	Subject Device		Predicate Device	Reference Device
	Specification of Type 4 resin	DENTCA Base		Halley Resin*	DENTCA Denture Base II
		Hi-Impact	Premium		
Flexural Modulus	≥ 2000 MPa	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD
Flexural Strength	≥ 65 MPa	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD
Water Sorption	< 32 µg/mm^3	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD
Water Solubility	< 1.6 µg/mm^3	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD	Meet the consensus STD
Maximum Intensity Factor	≥ 1.9 MPa m$^{1/2}$	Meet the consensus STD	Not claimed	Meet the consensus STD	Not claimed
Total Fracture Work	≥ 900 J/m^2	Meet the consensus STD	Not claimed	Meet the consensus STD	Not claimed
Residual Methylmethacrylate	< 2.2%	Not Detectable	Not Detectable	Meet the consensus STD	Not Detectable

* Data cited from the predicate device K190043 510(k) Summary, Table 5.2

Conclusions

The above comparison of the subject and predicate devices shows that both devices fabricate the denture in the same manner, via automated application of a light-curable resin in an additive 3D printer.

The subject and predicate devices have the same intended use, similar indications for use, and comprise the same technological characteristics.

Furthermore, the non-clinical data support the safety and effectiveness of the device and demonstrates that DENTCA Base Resin should perform as intended in the specified use conditions.

In conclusion, DENTCA Base Resin is substantially equivalent to the legally marketed Halley Resin, and thus warrants clearance from FDA for premarketing activities in the United States.