July 1, 2026

Dentca, Inc.
Jason Lee
Official Correspondent
17742 Cowan
Irvine, California 92614

Re: K261474
Trade/Device Name: DENTCA Tru Flexible
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: May 4, 2026
Received: May 4, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K261474

Device Name
DENTCA Tru Flexible

Indications for Use *(Describe)*
DENTCA Tru Flexible is a light-curable resin indicated for the fabrication of removable flexible full and partial denture bases in dental laboratories or dental office. The material is also indicated for fabrication of try-in dentures for clinical evaluation and as an aid for bonding denture teeth to denture bases.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter

DENTCA, INC.
17742 Cowan,
Irvine, CA 92614

Phone: 855-933-6822
Fax: 424-558-8738
Contact Person: Jason Lee
Date Prepared: December 15, 2025

Device Classification

Proprietary Name:	DENTCA Tru Flexible
Trade Name:	DENTCA Tru Flexible
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:	K250617
Clearance Date:	April 29, 2025
Trade Name:	Apex Flex
Actual Trade Name:	Apex Flex
Manufacturer:	SprintRay
Regulation Number:	21 CFR 872.3760
Product Code:	EBI

Reference Device

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

510(k) Number:	K220042
Clearance Date:	November 17, 2022
Actual Trade Name:	DENTCA Base Hi-Impact
Manufacturer:	DENTCA, Inc.
Regulation Number:	21 CFR 872.3760
Product Code:	EBI

Device Description

DENTCA Tru Flexible is a light-curable resin intended to fabricate removable flexible dentures bases 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 Tru Flexible can also be utilized to bond printed teeth onto denture base.

Indications For Use

DENTCA Tru Flexible is a light-curable resin indicated for the fabrication of removable flexible full and partial denture bases in dental laboratories or dental office. The material is also indicated for fabrication of try-in dentures for clinical evaluation and as an aid for bonding denture teeth to denture bases.

Comparison of Technological Characteristics With Predicate

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

Table 1 Comparison of Technical Features

	Subject Device	Predicate Device	Reference Device	Similarities and Differences
Device Names	**DENTCA Tru Flexible**	**SprintRay Apex Flex**	**DENTCA Base Hi-Impact**	**NA**
Regulation & Product Code	872.3760; EBI	872.3760; EBI	872.3760; EBI	Same Classification
Intended Use	Fabrication of removable flexible denture bases and dental prosthesis.	Fabrication and repair of partial dentures	Fabrication and repair of base plates for removable dental prosthetic appliances	Similar Intended Use
Indications For Use	DENTCA Tru Flexible is a light-curable resin indicated for the fabrication of removable flexible full and partial denture bases in dental laboratories or dental office. The material is also indicated for fabrication of try-in dentures for clinical evaluation and as an aid for bonding denture teeth to denture bases.	SprintRay Apex Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work.	DENTCA Base Hi-Impact 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 other dental appliances. DENTCA Base Hi-Impact can	Similar Indications for Use

			also be used for the fabrication of try-in dentures for the evaluation before fabricating the final dentures. Fabrication of these prosthesis with DENTCA Base Hi-Impact requires a digital denture file, additive printer, and curing light equipment. DENTCA Base Hi-Impact can be utilized as an aid in bonding the denture teeth onto denture base.	

Device Description

Resin Type	Type 4, Light-cure resin	Type 4, Light-cure resin	Type 4, Light-cure resin	Same Type
Chemical Composition	Methacrylate-based resins with photoinitiator, and pigments	Acrylate-based resins including photoinitiator and pigments	Methacrylate-based resins with photoinitiator, and pigments	All similar chemical system.

Fabrication Method of Denture Base	Automated 3D printing of resin in multiple layers, and post-cure in light curing unit	Automated 3D printing of resin in multiple layers, and post-cure in oven curing unit	Automated 3D printing of resin in multiple layers, and post-cure 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	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.

Non-Clinical and/or Clinical Tests Summary

The following non-clinical testing conducted and its data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for DENTCA Tru Flexible 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 Test

Bench test for DENTCA Tru Flexible was conducted for conformity in accordance with ISO 20795-1:2013 Dentistry – Base polymers – part 1: Denture base polymers, as recognized by FDA. The battery of testing included the following tests:

- ✓ Ultimate Flexural Strength
- ✓ Flexural Modulus

- ✓ Maximum Stress Intensity Factor
- ✓ Total Fracture Work
- ✓ Color Stability
- ✓ Freedom from Porosity
- ✓ Bonding to Polymer Teeth
- ✓ Water Sorption
- ✓ Water Solubility
- ✓ Printing Accuracy

DENTCA Tru Flexible consistently performed as anticipated, yielding satisfactory outcomes.

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 Tru Flexible should perform as intended in the specified use conditions.

In conclusion, DENTCA Tru Flexible is substantially equivalent to the legally marketed SprintRay Apex Flex, and thus warrants clearance from FDA for premarketing activities in the United States.