June 2, 2026

Carbon, Inc.
% Michael Nilo
President, Principal Consultant
Nilo Medical Consulting Group, LLC
3706 Butler St.
Suite #313
Pittsburgh, Pennsylvania 15201

Re: K260569
Trade/Device Name: DB 4000 High Impact Denture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: May 6, 2026
Received: May 7, 2026

Dear Michael Nilo:

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
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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)*
K260569

Device Name
DB 4000 High Impact Denture Base

Indications for Use *(Describe)*
DB 4000 High Impact Denture Base is indicated for the fabrication of dental devices for fully edentulous patients using additive manufacturing on 3D printers. This includes the fabrication of full removable dentures, overdentures, try-ins and temporary dentures. Fabrication of dental devices using DB 4000 High Impact Denture Base requires a digital denture file, digital light synthesis (DLP) 3D printer and curing light equipment. DB 4000 High Impact Denture Base can be utilized as an aid in bonding the denture teeth to the 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.

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.

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K260569

510(k) Summary

SUBMITTER:

Carbon Inc
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Contact: Gina Policastro
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Date Prepared: February 18, 2026

DEVICE CLASSIFICATION

Trade Name: DB 4000 High Impact Denture Base
Common Name: Denture Base, Prescription
Regulation Number: 21 CFR 872.3760
Classification Name: Denture relining, repairing, or rebasing resin
Product Code: EBI
Regulatory Class: II

PREDICATE DEVICE

The following predicate and reference devices are legally marketed, post-amendment devices:

Predicate Number: K220042
Predicate Name: DENTCA Base Resin
Predicate Product Code: EBI

Reference Number: K220979
Reference Name: SprintRay Dental Base
Reference Product Code: EBI

DEVICE DESCRIPTION

DB 4000 High Impact Denture Base is a photocurable, methacrylate-based dental resin designed for fabrication of dental prosthetics using additive manufacturing on Digital Light Processing (DLP) 3D printers (wavelength = 385nm). DB 4000 High Impact Denture Base is intended to be used within a computer-aided design and manufacturing (CAD/CAM) digital dentistry system that includes a 3D scanner, design software, 3D printer, and a UV post-cure unit (wavelength = 385-405nm). DB 4000 High Impact Denture Base is intended exclusively for professional dental work for the fabrication of dental devices for fully edentulous patients, which includes full removable dentures, overdentures, try-ins and temporary dentures. DB 4000 High Impact Denture Base is designed to meet the ISO 20795-1:2013

standard for high impact denture base material and is consistent with the expectations described in the FDA Guidance *Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway*.

DB 4000 High Impact Denture Base is offered in the following shades: Light Pink, Original Pink, Dark Reddish Pink, Dark Meharry

INDICATIONS FOR USE

DB 4000 High Impact Denture Base is indicated for the fabrication of dental devices for fully edentulous patients using additive manufacturing on 3D printers. This includes fabrication of fully removable dentures, overdentures, try-ins and temporary dentures. Fabrication of dental devices using DB 4000 High Impact Denture Base requires a digital denture file, digital light synthesis (DLP) 3D printer and curing light equipment. DB 4000 High Impact Denture Base can be utilized as an aid in bonding the denture teeth to the denture base.

COMPARISON BETWEEN TECHNOLOGY OF DEVICES

Both the subject and predicate resins are photocurable for dental prosthetics using additive manufacturing with a digital dental file for the patient.

Table 1, below, presents a comparison between the technologies of the subject, predicate, and reference devices.

Table 1: Technological Comparison Table

	Subject Device	**Predicate Device**	**Reference Device**	**Similarities and Differences**
Device Names	**DB 4000 High Impact Denture Base**	**DENTCA Base Resin**	**SprintRay Denture Base**	**N/A**
510K number		K220042	K220979	N/A
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 appliances	Same intended use
Indications for Use	DB 4000 High Impact Denture Base is indicated for the fabrication of dental devices for fully edentulous patients using additive manufacturing on 3D printers. This includes the fabrication of full removable dentures, overdentures, try-ins and temporary dentures. Fabrication of dental devices using DB 4000 High Impact Denture Base requires a digital denture file, digital light synthesis (DLP) 3D printer and curing light equipment. DB 4000 High Impact Denture Base can be utilized as an aid in bonding the denture teeth to the denture base.	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 the	SprintRay Denture Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material. Fabrication of dental prosthetics with SprintRay Denture Base resin requires computer-aided design and manufacturing system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, 3D printer, and curing light equipment	All resins are photo-curable resins indicated for the fabrication and repair of dental devices using digital denture files, 3D printers and light curing devices.

		denture base		
Resin Type	Type 4, Ligh-cure resin	Type 4, Light-cure resin	Type 4, Light-cure resin	Same resin type
Chemical Composition	Acrylate-based photocurable resins with pigments, photoinitiator.	Acrylate-based resins with photoinitiator, and pigments	Acrylate-based photocurable resins with pigments, photoinitiator and silica filler.	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 requirements
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 of the subject, predicate, and reference devices shows that these devices are chemically similar and are fabricated in the same manner, using digital denture files, 3D printing and light curing units. The subject devices and the predicate device have the same intended use, similar indications for use and comprise the same technological characteristics.

PERFORMANCE DATA

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

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with expectation of FDA Guidance *Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway*. The denture base is considered tissue contacting (mucosal membrane) for a period > 30 days.

Software Verification and Validation Testing

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

Bench Testing

Bench tests for the DB 4000 High Impact Denture Base was conducted in accordance with ISO 20795-1:2013, as recognized by FDA. Performance testing was conducted per recommendations of FDA Guidance *Denture Base Resins – Performance Criteria for Safety and Performance Based Pathway*. The data in **Table 2** support a conclusion that the subject device meets the requirements per ISO 20795-1 standard.

Table 2: ISO 20795-1 Testing Table

	ISO 20795-1	Subject Device
	Specification of Type 4 resin	**DB 4000 High Impact Denture Base**
Flexural Modulus	≥2000 MPa	Meets the consensus STD
Flexural Strength	≥65 MPa	Meets the consensus STD
Water Sorption	<32 µg/mm3	Meets the consensus STD
Water Solubility	<1.6 µg/mm3	Meets the consensus STD
Maximum Intensity Factor	≥1.9 MPa/m	Meets the consensus STD
Total Fracture Work	≥900 J/m2	Meets the consensus STD
Residual Methylmethacrylate	<2.2%	Not detectable
Freedom from Porosity	% specimen should not show voids that are observed through visible inspection	Meets the consensus STD
Color stability	2 out of 3 people with normal color vision must independently determine that no more than a slight change in color is observed.	Meets the consensus STD

CONCLUSIONS

The above comparison of the subject and predicate and reference devices show that these devices are chemically similar and are fabricated in the same manner, using digital denture files, 3D printing and light curing units. The subject device and predicate and reference devices have the same intended use, similar indications for use, and comprise the same technological characteristics.

Additionally, the non-clinical data support the safety and effectiveness of the device and demonstrates that DB 4000 High Impact Denture Base should perform as intended in its specified use conditions for the fabrication of dental devices for fully edentulous patients.

DB 4000 is substantially equivalent to the legally marketed DENTCA Denture Base resin and SprintRay Denture Base resin.