June 27, 2025

Dent4You AG
Oliver Ashe
Regulatory Affairs Manager
Bahnhofstrasse 2
Heerbrugg, SG 9435
SWITZERLAND

Re: K250969
Trade/Device Name: Jet Bite; Jet Blue Bite Fast; Jet Blue Bite Superfast
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: March 12, 2025
Received: March 31, 2025

Dear Oliver Ashe:

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
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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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)*

K250969

Device Name

JET BITE;
JET BLUE BITE FAST;
JET BLUE BITE SUPERFAST

Indications for Use *(Describe)*

JET BITE & JET BLUE BITE are intended for the registration of occlusion in cases where relationship between the relative positions of maxilla and mandible is required.

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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510(k) #: K250969

510(k) Summary

Prepared on: 2025-04-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dent4You AG
Applicant Address	Bahnhofstrasse 2 Heerbrugg SG 9435 Switzerland
Applicant Contact Telephone	41717575424
Applicant Contact	Mr. Oliver Ashe
Applicant Contact Email	oliver.ashe@coltene.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	JET BITE; JET BLUE BITE FAST; JET BLUE BITE SUPERFAST
Common Name	Impression material
Classification Name	Material, Impression
Regulation Number	872.3660
Product Code(s)	ELW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190571	StoneBite and StoneBite scan	ELW

Device Description Summary

21 CFR 807.92(a)(4)

Jet Bite and Jet Blue Bite are two component impression materials based on vinylpolysiloxanes used for the registration of occlusion between the maxilla and mandible. Jet Bite and Jet Blue Bite are mixed during application and applied directly to the teeth, after which the mandible is moved into central occlusion making an impression.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

JET BITE & JET BLUE BITE are intended for the registration of occlusion in cases where relationship between the relative positions of maxilla and mandible is required.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are similar between the subject device and predicate.

Technological Comparison

21 CFR 807.92(a)(6)

JET BITE & JET BLUE BITE (subject device) and StoneBite and StoneBite scan (predicate device) are both addition silicone based impression materials (vinylpolysiloxane), with the same intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing was carried out in accordance with the FDA guidance document, "Dental Impression Materials – Performance Criteria for Safety and Performance Based Pathway", issued September 30, 2024. Performance testing in this guidance is based on the FDA recognised version of ISO 4823

As per the requirements set out in FDA guidance document, "Dental Impression Materials – Performance Criteria for Safety and Performance Based Pathway", for a Type B impression material, the following performance tests were carried out on the subject device: Linear dimensional change, Compression set & Hardness (Shore A)

We have carried out testing relevant for Type B impressions materials as set out in "Dental Impression Materials - Performance Criteria for Safety and Performance Based Pathway", we have been able to declare conformity to ISO 4823, therefore demonstrating the device is as safe and effective as the predicate device