November 15, 2024

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

Re: K242360
Trade/Device Name: Speedex Light Body; Speedex Medium; Speedex Putty; Speedex Putty Soft; Speedex Universal Activator
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: August 9, 2024
Received: August 9, 2024

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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)*

K242360

Device Name

Speedex Light Body;
Speedex Medium;
Speedex Putty;
Speedex Putty Soft;
Speedex Universal Activator

Indications for Use *(Describe)*

Speedex putty/putty soft
- Primary impression in the putty-wash Impression technique
- Pick-up impression in the simultaneous mixing technique
- Impressions for study models, orthodontic models, keys and protective isolation of teeth during fitting of prostheses

Speedex light body
- Correction material for the correction impression technique
- Syringe material for the two-phase impression technique
- Impression material for relining

Speedex medium
- Complete and partial prosthetics, correction material for the correction impression technique
- Monophase impression technique, simultaneous mixing technique
- Liner impression material

Speedex Universal Activator
- Activator for Speedex putty; Speedex putty soft; Speedex light body; Speedex medium, for creating dental impressions

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.

510(k) #: K242360

510(k) Summary

Prepared on: 2024-08-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dent4 YouAG
Applicant Address	Bahnhofstrasse 2 Heerbrugg SG 9435 Switzerland
Applicant Contact Telephone	4 1 71 757 54 24
Applicant Contact	Mr. Oliver Ashe
Applicant Contact Email	oliver.ashe@coltene.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Speedex Light Body; Speedex Medium; Speedex Putty; Speedex Putty Soft; Speedex Universal Activator
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
K220097	PRESIDENT The Original	ELW

Device Description Summary

21 CFR 807.92(a)(4)

Speedex is two-component impression material based on polysiloxanes. Speedex is intended for the recording of the current physical situation in a patient's mouth for the purpose of repairing, reshaping or replacing the patient's teeth. After mixing of a base and activator, the Speedex Materials form pastes which are used individually or in combination as dental impression material, usually together with a standard commerical or individual impression tray, using conventional impression techniques.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Speedex putty/putty soft
- Primary impression in the putty-wash Impression technique
- Pick-up impression in the simultaneous mixing technique
- Impressions for study models, orthodontic models, keys and protective isolation of teeth during fitting of prostheses

Speedex light body
- Correction material for the correction impression technique
- Syringe material for the two-phase impression technique
- Impression material for relining

Speedex medium

- Complete and partial prosthetics, correction material for the correction impression technique
- Monophase impression technique, simultaneous mixing technique
- Liner impression material

Speedex Universal Activator
- Activator for Speedex putty; Speedex putty soft; Speedex light body; Speedex medium, for creating dental impressions

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)

Speedex (subject device) and PRESIDENT the Original (predicate device) are both two component room temperature vulcanising silicones, provided in a range of viscosities with the same intended use. The precise composition of the two devices represents a technological difference. Speedex is composed of polysiloxanes and filler materials, whereas PRESIDENT the Original consists of polyvinylsiloxanes and filler materials. This difference does not raise different questions of safety and effectiveness between the subject and predicate device.

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

Performance testing as was conducted to verify that the device complies with the requirements of ISO 4823:2021, and the same testing was carried out on the predicate device to help establish substantial equivalence. These tests include consistency, working time, detail reproduction, linear dimensional change, compatibility with gypsum, elastic recovery, and strain in compression. Additionally biocompatibility testing to the requirements of ISO 10993-5 and 10993-10 as well as shelf life testing was carried out.

Based on the non-clinical performance data, the proposed device Speedex is as safe, as effective and performs as well as the predicate Device PRESIDENT the Original.