September 17, 2025

Kamemizu Chemical Industry Co., Ltd
Tomohiro Kinoshita
Quality Assurance Manager
17-16
Toyosato
Neyagawa, 5720071
JAPAN

Re: K252035
Trade/Device Name: DENTURE SOFT EX (Pink set); DENTURE SOFT EX (White set); DENTURE SOFT EX (Pink powder); DENTURE SPFT EX (White powder); DENTURE SOFT EX (Liquid); DENTURE SOFT EX (Trial kit Pink); DENTURE SOFT EX (Trial kit White)
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: June 30, 2025
Received: September 5, 2025

Dear Tomohiro Kinoshita:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252035

Device Name
DENTURE SOFT EX (Pink set); DENTURE SOFT EX (White set); DENTURE SOFT EX (Pink powder); DENTURE SPFT EX (White powder); DENTURE SOFT EX (Liquid); DENTURE SOFT EX (Trial kit Pink); DENTURE SOFT EX (Trial kit White)

Indications for Use *(Describe)*
It is a soft acrylic resin used to line the denture base. It is a tissue conditioner. By lining the mucous membrane side of dentures, it is used for temporary relining, tissue conditioning, and obtaining functional 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.

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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510(k) #: K252035

510(k) Summary

Prepared on: 2025-09-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	KAMEMIZU CHEMICAL INDUSTRY CO., LTD
Applicant Address	17-16 Toyosato Neyagawa 5720071 Japan
Applicant Contact Telephone	+81-72-826-7720
Applicant Contact	Mr. Tomohiro Kinoshita
Applicant Contact Email	kinoshita@kamemizu.co.jp

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DENTURE SOFT EX (Pink set); DENTURE SOFT EX (White set); DENTURE SOFT EX (Pink powder); DENTURE SPFT EX (White powder); DENTURE SOFT EX (Liquid); DENTURE SOFT EX (Trial kit Pink); DENTURE SOFT EX (Trial kit White)
Common Name	Denture relining, repairing, or rebasing resin
Classification Name	Resin, Denture, Relining, Repairing, Rebasing
Regulation Number	872.3760
Product Code(s)	EBI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K070698	COE COMFORT	EBI

Device Description Summary

21 CFR 807.92(a)(4)

DENTURE SOFT EX is a soft lining material for removable dentures.
It is a soft acrylic resin used to line the denture base. It is a tissue conditioner. By lining the mucous membrane side of dentures, it is used for temporary relining, tissue conditioning, and obtaining functional impressions.
The device consists of powder and liquid. The powder contains acrylic polymer (POLY (ETHYL METHACRYLATE)) and others. The liquid contains plasticizer, ethanol and others.
The powder and liquid are mixed when it is used and starts gelation, forms soft acrylic resin.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

It is a soft acrylic resin used to line the denture base. It is a tissue conditioner. By lining the mucous membrane side of dentures, it is used for temporary relining, tissue conditioning, and obtaining functional impressions.

Indications for Use Comparison

21 CFR 807.92(a)(5)

It is the same. Indications for use of the predicate device includes that of the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

The predicate device consists of the powder (mainly poly (ethyl methacrylate) and the liquid (mainly plasticizer (benzyl benzoate) and ethanol). Mixing the powder and liquid causes the liquid to permeate the powder, starting gelation and form soft acrylic resin. The subject device uses the same composition and technical characteristics.

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

Bench testing was done in accordance with ISO 10139-1:2018.
The subject device has performance meeting ISO 10139-1:2018.

The subject device and the predicate device have the same performance. It means the subject device is as safe, as effective, and performs as well as predicate device.