June 3, 2025

Clemde Sa De Cv
Cabrera Francisco
General Manager
Mexico City, 07800
MEXICO

Re: K242897
Trade/Device Name: Partial Flex
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin.
Regulatory Class: Class II
Product Code: EBI, MQC
Dated: April 4, 2025
Received: May1, 2025

Dear Cabrera Francisco:

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

Submission Number *(if known)*

K242897

Device Name

PARTIAL FLEX

Indications for Use *(Describe)*

Partial Flex® is indicated for the fabrication of partial or full removable dentures, as well oclusional splints or night guards

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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"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."

K 242897

Section 6 - *510(k) Summary*

1. Submitter

APPLICANT: Av la Fortuna #136, Industrial,
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Internet: www.clemde.com

CONTACT PERSON: Mariana Correa
Tel.:956 414 1295
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2. Device Name

Trade Names: Partial Flex

Common Name: Dental Resin

Classification Name: EBI Denture Relining, Repairing, or Rebasing Resin

3. Predicate Device

Partial Flex is substantially equivalent to the following predicate devices already cleared by the FDA:

Predicate Device	510(k) Number	510(k) Holder
TCS UNBREAKABLE	K053060	THERMOPLASTIC CONFORT SYSTEM

4. Description of the Device

4.1. Partial Flex

Partial Flex® dental resin is a polymer base material used for the fabrication of partial removable dentures and prosthesis. Partial Flex is made from a resin of polypropylene that is designed and manufactured for injection molding. Partial Flex® is available in two shades as a granular material (so-called pellets) contained in an aluminum tube with 27 g or in a plastic bag of 250 g. In addition to high biocompatibility, Partial Flex® material features hypoallergenic properties, no risk of discoloration and the dental prosthesis made are unbreakable, which differentiates the from acrylic materials.

4.2. Partial Flex Plastic bag

The resin material is pigmented in one color and without pigment presentation:

300116 Light pink
300118 Natural color (without pigment)

4.3. Partial Flex Aluminum tube

The resin material is pigmented in one color and without pigment presentation:

300073 Light pink
300079 Natural color (without pigment)

5. Indications for Use

5.1. Partial Flex

Partial Flex® is indicated for fabrication of partial or full removable dentures, as well oclusional splints or night guards.

6. Technological Characteristics

	NEW DEVICE	PREDICATE DEVICE
510(k) Submitter/ Holder	**CLEMDE**	**THERMOPLASTI CONFORT SYSTEM**
Trade Name	**Partial Flex**	**TCS UNBREAKABLE**
510(k) Number	K242897	K053060
Material	Resin of polypropylene	polyamide
Shape	Pellets	Granulate – resin
Indications for use	Partial Flex® is indicated for fabrication of partial or full removable dentures, as well oclusional splints or night guards.	Fabrication and repair of removable dental prosthetic devices, such as full and partial dentures, orthodontic devices, occlusal splints, and guards.
Shape	Pellet	granular resin

Color stability	The material complies with the requirements	-
Translucency	The material complies with the requirements	-
Freedom from porosity	The material complies with the requirements	-
Ultimate Flexural Strength	The material complies with the requirements	Physical testing meets standard for dental base polymers
Flexural modulus	The material complies with the requirements	Physical testing meets standard for dental base polymers
Maximum stress intensity factor for materials with improved impact resistance	The material complies with the requirements	Physical testing meets standard for dental base polymers
Total fracture work	The material complies with the requirements	Physical testing meets standard for dental base polymers
Sorption	The material complies with the requirements	Physical testing meets standard for dental base polymers
Solubility	The material complies with the requirements	Physical testing meets standard for dental base polymers

7. Nonclinical Performance Testing

Partial Flex® has been tested in the following test modes:

- Bench testing per Iso 20795.
- Biocompatibility:
  - INTRACUTANEOUS INJECTION TEST - per Iso 10993 passed the acceptence criteria
  - KLIGMAN MAXIMIZATION TEST - per Iso 10993 passed the acceptence criteria
  - L929 MEM ELUTION TEST - per Iso 10993 passed the acceptence criteria

The results of this nonclinical testing show that the PARTIAL FLEX is sufficient for its intended to used and is substantially equivalent to the legally marketed predicate device.

8. Substantial Equivalence Summary / Conclusion

ConclusionBased on available 510(k) information provided here in, Partial Flex is considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design, and performance specifications.