November 27, 2023

Clemde Sa De Cv
Francisco Cabrera
General Manager
Av La Fortuna 136
Mexico City, 07800
MEXICO

Re: K233171
Trade/Device Name: PF Keep; Cad Cam Keep Block
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, EBG, EBF
Dated: September 25, 2023
Received: September 28, 2023

Dear Francisco Cabrera:

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.

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
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.

Submission Number *(if known)*

K233171

Device Name

PF KEEP;
CAD CAM KEEP BLOCK

Indications for Use *(Describe)*

PF KEEP / CAD CAM BLOCK IS A THERMO PLASTIC MATERIAL. THEY ARE INTENDED TO BE USED FOR THE MAANUFACTURE OF:
I) FULL AND PARTIAL REMOVABLE DENTURES AND IMPLANT OVERDENTURES
II)COPINGS, SUBSTRUCTURES (CEMENTED OR UNCEMENTED), FRAMEWORKS FOR PERMANENT AND TRANSITIONAL ANTERIOR OR POSTERIOR CROWNS AND BRIDGEWORKS.

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 233171

Section 6 - *510(k) Summary*

1. Submitter

SUBMITTER: **CLEMDE S.A. DE C.V.**

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México City 07800
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Date prepared: September 25, 2023

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2. Device Name

Trade Names: PF KEEP - CAD CAM PEEK BLOCK

Common Name: Dental Resin

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

3. Predicate Device

PF KEEP ® and CAD CAM PEEK BLOCK are substantially equivalent to the following predicate device already cleared by the FDA:

510 K Number	Predicate Device	Manufacture
K160918	Juvora TM dental disc	Juvora Ltd

4. Description of the Device

4.1. PF KEEP

PF KEEP is a thermoplastic polymer, made from the polymer peek, is available as a granular material (so-called pellets) contained in plastic box with 45 g. that are used for manufacture of removable dental protheses. In case of CAD CAM PEEK BLOCK is for used with CAD CAM techniques. The material is provided nonsterile, without any accessories, and is a single use.

The CAD CAM PEEK BLOCK are provided in different sizes.

900033 CAD CAM PEEK BLOCK 14 MM
900034 CAD CAM PEEK BLOCK 16 MM
900035 CAD CAM PEEK BLOCK 18 MM
900036 CAD CAM PEEK BLOCK 20 MM
900037 CAD CAM PEEK BLOCK 22 MM

5. Indications for Use

5.1. PF KEEP / CAD CAM PEEK BLOCK

PF KEEP / CAD CAM PEEK BLOCK is a thermoplastic material. they are intended to be used for manufacture of:

I) Full and partial removable dentures and implant overdentures.

II) Copings, substructures (cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgeworks.

6. Technological Characteristics

	NEW DEVICE		**PREDICATE DEVICE**	
510(k) Submit-ter/ Holder	**CLEMDE SA DE CV**		**JUVORA, Ltd**	
Trade Name	**PF KEEP**	**CAD CAM PEEK BLOCK**	**Juvora TM dental disc**	
510(k) Number	-		K160918	
Material	PEEK		PEEK	
Shape	Granulate – Pellets	Disc		Disc
Indications for use	PF PEEK is a thermoplastic MATERIAL. They are intended to be used for the manufacture of: I) full and partial removable dentures and implant overdentures.		The Juvora Dental Disc is a thermoplastic dental disc. They are intended to be used for the manufacture of: i) full and partial removable dentures and implant overdentures.	

	II) copings, substructures (Cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgework.	ii) copings, substructures (Cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgework.
Ultimate Flexural Strength	162 Mpa	165 MPa
Flexural modulus	3530 MPa	3995 MPa
Stress Intensity Factor	6.81 MPa m2	-
Total fracture work	10846 J/m^2	--
Water sorption	5 µg/mm3	5 µg/mm^3
Solubility	0.04 µg/mm3	--

7. Nonclinical Performance Data

PF KEEP / CAD CAM KEEP BLOCK has been tested in the following test modes:

- Bench testing per Iso 20795.
- Biocompatibility per Iso 10993

The results of this nonclinical testing show that the PF KEEP/ CAD CAM PEEK BLOCK is sufficient for its intended to used and is substantially equivalent to the legally marketed predicate device.

8. Substantial Equivalence Summary / Conclusion

Based on the available information provided, PF KEEP ® and CAD CAM PEEK BLOCK are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, and performance specifications.