October 24, 2024

Keystone Industries
Caleb Barylski
Regulatory Affairs Manager
480 S. Democrat Road
Gibbstown, New Jersey 08027

Re: K241089
Trade/Device Name: KeyPrint KeyDenture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 26, 2024
Received: September 26, 2024

Dear Caleb Barylski:

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)*

K241089

Device Name

KeyPrint KeyDenture Base

Indications for Use *(Describe)*

KeyPrint KeyDenture Base is a photopolymer resin indicated for the 3D fabrication of denture bases, including full and partial removable dentures, in dental laboratories. Fabrication requires a computer-aided design and manufacturing (CAD/CAM) system and 3D printer.

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) #: K241089

510(k) Summary

Prepared on: 2024-09-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Keystone Industries
Applicant Address	480 S. Democrat Road Gibbstown NJ 08027 United States
Applicant Contact Telephone	856-548-5205
Applicant Contact	Mr. Caleb Barylski
Applicant Contact Email	cbarylski@keystoneind.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KeyPrint KeyDenture Base
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
K203641	E-Denture Pro	EBI
K191427	Halley Resin System	EBI

Device Description Summary

21 CFR 807.92(a)(4)

KeyPrint KeyDenture Base is designed for additive manufacturing in vat polymerization 3D printers utilizing wavelengths between 385nm-405nm. KeyDenture Base is indicated for the fabrication of oral denture appliances for fully and partially edentulous patients. KeyDenture Base is intended to be used within a computer-aided and manufacturing (CAD/CAM) digital dentistry system that includes a 3D scanner, design software, 3D printer, and post-cure unit. For any components that are used in conjunction with the KeyDenture Base resin, the user should review all applicable product labeling including Instructions for Use, user manuals, and other associated labeling. Strict adherence to all labeling is critical in assuring a safe and effective printed appliance.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

KeyPrint KeyDenture Base is a photopolymer resin indicated for the 3D fabrication of denture bases, including full and partial removable dentures, in dental laboratories. Fabrication requires a computer-aided design and manufacturing (CAD/CAM) system and 3D printer.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for Use: Similar
The subject and predicate device are both light-curable/photopolymer resins indicated for the fabrication of denture bases using CAD/CAM systems. The subject is indicated for full and partial dentures, while the predicate is for full dentures. The reference device is also indicated for the same fabrication while including full and partial dentures. The indications are similar and do not create a new intended use.

Intended Use: Identical to predicate and reference devices.

Technological Comparison 21 CFR 807.92(a)(6)

Design/Principles of Operation - Similar; the subject device is designed as a denture base for removable full and partial dentures while the predicate is designed for removable full dentures. The reference device is also designed for removable full and partial dentures, using the same materials, similar indications, and same manufacturing methods. The addition of the partial design to the subject compared to the predicate does not create a new intended use and does not raise issues of safety and effectiveness.
Design/Removable - Identical - both subject and predicate are removable dental appliances.
Materials - Identical - both subject and predicate are manufactured from light-curable acrylate resin.
Manufacturing Type - Identical - both subject and predicate utilize additive manufacturing in 3D printers.

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

Nonclinical performance testing was conducted for physical and biocompatible properties:

Physical:
Performance of the physical properties of the subject device were completed per ISO 20795-1:2013 - Dentistry - Base polymers - Part 1: Denture base polymers. The following tests were completed successfully:
-Colour stability
-Ultimate Flexural Strength
-Flexural Modulus
-Fracture Toughness
-Residual methyl methacrylate monomer
-Bonding to synthetic teeth
-Water sorption
-Water solubility

Additional performance testing was completed per ASTM D348-14 (tensile properties) and ASTM D648-16 (deflection temperature).

Biocompatibility:
Testing was completed according to ISO 10993, confirming the subject KeyDenture Base is biocompatible and meets the requirements for a permanent (>30 days) device in contact with the mucosal membrane.

Clinical Testing:
Not Applicable

Conclusion of Safety and Effectiveness:
The subject device, KeyDenture Base, has an identical Intended Use and similar Indications for Use and technological characteristics as the predicate device, E-Denture Pro, and reference, Halley Resin System. Any differences in technology and performance have been tested to determine equivalence to the predicate device, and the information provided herein demonstrates:
• any differences do not raise new questions of safety and effectiveness; and
• the proposed device is at least as safe and effective as the legally marketed predicate device.