July 8, 2026

Formlabs Ohio, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K262300
Trade/Device Name: Denture Base Resin V2
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture relining, repairing, or rebasing resin
Regulatory Class: Class II
Product Code: EBI
Dated: July 7, 2026
Received: July 7, 2026

Dear Prithul Bom:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262300

Please provide the device trade name(s).

Denture Base Resin V2

Please provide your Indications for Use below.

Denture Base Resin V2 is a light-curable resin indicated for the fabrication of denture bases, including full and partial removable dentures, implant overdentures, and other dental appliances. Denture Base Resin V2 is indicated to treat patients with complete or partial edentulism.

Please select the types of uses.

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

510(k) #: K262300

510(k) Summary

Prepared on: 2026-07-06

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Formlabs Ohio, Inc.
Applicant Address	27800 Lemoyne Rd Millbury OH 43447 United States
Applicant Contact Telephone	7813368303
Applicant Contact	Ms. Paige Johnson
Applicant Contact Email	paige.johnson@formlabs.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Denture Base Resin V2
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
K231578	Lucitone Digital Print 3D Denture Base	EBI

Device Description Summary

21 CFR 807.92(a)(4)

Denture Base Resin V2 is a light-curable resin intended for the fabrication of denture bases, including full and partial removable dentures, to restore function and aesthetics. The resin is intended to be processed exclusively using a validated computer-aided design and manufacturing (CAD/CAM) workflow and subsequent post-processing steps as specified in the manufacturer's instructions for use. Denture Base Resin V2 can be utilized as an aid in bonding denture bases to printed denture teeth, as well as for repair using traditional techniques.

Dental professionals are responsible for verifying the suitability of the printed denture base for the specific patient and clinical scenario.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Denture Base Resin V2 is a light-curable resin indicated for the fabrication of denture bases, including full and partial removable dentures, implant overdentures, and other dental appliances. Denture Base Resin V2 is indicated to treat patients with complete or partial edentulism.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Formlabs Ohio, Inc., submits that the Subject device, Denture Base Resin V2, is Substantially Equivalent to the legally marketed Predicate device, Lucitone Digital Print 3D Denture Base (K231578).

The Indications for Use of the Subject and Predicate devices are substantially equivalent. The Subject device's inclusion of the phrase "to treat patients with complete or partial edentulism" is a clinical description of the patient population already inherent in the fabrication of full and partial dentures. This minor difference in phrasing provides additional clinical clarity but does not represent a change in

intended use or the target population compared to the legally marketed Predicate.

Technological Comparison

21 CFR 807.92(a)(6)

The Subject and Predicate devices utilize the same fundamental technological characteristics. Both devices are methacrylate-based denture base resins that rely on a similar light polymerization mechanism and a validated workflow consisting of 3D printing, solvent washing, and post-curing to achieve a final cured state. While specific proprietary chemical formulations and processing parameters are distinct to each manufacturer, the Subject device's technology was validated against the performance criteria established for type 4 polymers in the FDA's Safety and Performance Guidance for Denture Base Resins. Any minor technological differences do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical bench testing was conducted for Denture Base Resin V2 in accordance with the FDA-recognized consensus standard ISO 20795-1:2013 for Type 4 denture base polymers and the criteria required under the FDA Guidance Document Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway. The material successfully passed all predefined acceptance criteria.

Not Applicable.

By successfully satisfying the established FDA performance criteria, it is concluded that Denture Base Resin V2 has met all requirements to demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate.