February 16, 2024

Formlabs Ohio, Inc.
Nathan Alt
Director, Regulatory Affairs & Quality Assurance
27800 Lemoyne Rd
Millbury, Ohio 43447

Re: K232087
Trade/Device Name: Dental LT Comfort Resin
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: January 18, 2024
Received: January 19, 2024

Dear Nathan Alt:

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,

FDA

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232087

Device Name
Dental LT Comfort Resin

Indications for Use *(Describe)*
Dental LT Comfort Resin when utilized to print dental or orthodontic appliances such as occlusal splints, nightguards, mouthguards and repositioners is indicated to treat patients diagnosed with Temporomandibular Joint Disorders (TMD) and/or Bruxism, respectively.

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.

5. 510(K) SUMMARY K232087

5.1. Submitter's Information

Name: Formlabs Ohio Inc.

Address: 27800 Lemoyne Rd
Millbury, OH 43447 USA

Phone Number: 419.837.9736

Contact Person: Nathan Alt
Director, Regulatory Affairs and Quality Assurance
nathan.alt@formlabs.com

Date Prepared: 15 February 2024

5.2. Device Name

Trade Name: Dental LT Comfort Resin

Common Name: Mouthguard, Prescription

Product Classification and Regulations:

Product Code: Classification Regulation Number and Risk Classification:

FDA Product Code MQC (Mouthguard, Prescription): Not subject to a Part 800 classification regulation; Risk Class- Unclassified
FDA Product Code KMY (Positioner, Tooth, Preformed): Regulated by 21 CFR § 872.5525; Risk Class - Class I (510(K) Exempt)

Panel:
Dental

5.3. Predicate Device:

Primary Predicate: Dental LT Clear V2 Resin (K222061)
Secondary Predicate: KeySplint Soft (K183598)

5.4. Description of Device and Intended Use

Dental LT Comfort Resin is a light-curable polymer-based resin designed for the fabrication of biocompatible, long-term use, removable dental and orthodontic appliances, such as occlusal splints, nightguards, mouthguards and repositioners by additive manufacturing.

5.5. Indication for use

Dental LT Comfort Resin when utilized to print dental or orthodontic appliances such as occlusal splints, nightguards, mouthguards and repositioners is indicated to treat patients diagnosed with Temporomandibular Joint Disorders (TMD) and/or Bruxism, respectively.

5.6. Statement on Substantial Equivalence

Dental LT Comfort Resin is substantially equivalent to the legally marketed predicate devices Dental LT Clear V2 Resin (K222061) and KeySplint Soft (K183598) with respect to product code, indications for use, materials of composition and chemical characterization, manufacturing technology and operating principle, performance characteristics and biocompatibility.

5.7. Technological Characteristics with the Predicate Device

Formlabs Dental LT Comfort Resin, Dental LT Clear V2 Resin and KeySplint Soft are used to fabricate patient-specific dental appliances such as mouthguards in a stereolithographic 3D printer using layer-by-layer additive manufacturing. After fabrication the printed part is post-processed by washing in an alcohol solution and then curing in an ultraviolet temperature-controlled curing unit. The finished part may undergo further post processing such as sanding, polishing, and disinfecting based on the user's requirements.

5.8. Performance Data

5.8.1 Biocompatibility Testing

Dental LT Comfort Resin was evaluated in accordance with *ISO 10993-1:2018*, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, and *ISO 7405:2018, Dentistry - Evaluation of biocompatibility of medical devices* used in dentistry. The testing showed that 3D printed samples of Dental LT Comfort are biocompatible and met the requirements for a Surface medical device with mucosal membrane contact for long term (> 30 days) duration. The endpoints assessed were physical and chemical information, cytotoxicity, sensitization, irritation, acute systemic toxicity, subacute systemic toxicity, subchronic/chronic systemic toxicity, implantation, material-mediated pyrogenicity and genotoxicity.

The results of the biological safety assessment, Dental LT Comfort Resin is considered to meet the requirements of the current ISO 10993-1:2018, ISO 14971:2019, 2023 FDA Biocompatibility Guidance, and European Medical Device: 2023/607 Regulation for a surface device that has long term (>30 days) contact with mucosal membrane.

5.8.2 Performance attributes

Dental LT Comfort Resin was tested to evaluate the performance requirements for orthodontic materials. Testing was performed to ISO 20795-2, ASTM D 638-14 and ASTM D 2240-15.

Results of the performance testing determined that Dental LT Comfort Resin performance attributes meet passing criteria or fall between the two predicate devices.

5.9. Conclusions

Formlabs Dental LT Comfort Resin has the same intended use and technological characteristics as the predicate devices. Based on the performance and biocompatibility testing, it is considered to be substantially equivalent to the predicate devices.