November 10, 2022

Formlabs Ohio, Inc.
Ritika Sharma
Regulatory Affairs Specialist
27800 Lemoyne Rd
Millbury, Ohio 43447

Re: K222061
Trade/Device Name: Dental LT Clear V2 Resin
Regulatory Class: Unclassified
Product Code: MQC, KMY, DYT
Dated: August 11, 2022
Received: August 15, 2022

Dear Ritika Sharma:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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)*
K222061

Device Name
Dental LT Clear V2 Resin

Indications for Use *(Describe)*
Dental Clear LT V2 Resin when utilized to print dental or orthodontic appliances such as occlusal splints, night guards, or mouth guards 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) SUMMARY

1. **Submitter's Name:**
Formlabs Ohio Inc.

2. **Address:**
27800 Lemoyne Rd
Millbury, OH 43447 USA

3. **Contact Person**
Ritika Sharma
Regulatory Affairs Specialist
Phone Number: 323-781-9504
Email: ritika.sharma@formlabs.com

4. **Date Prepared:**
November 8, 2022

5. **Trade Name:**
Dental LT Clear V2 Resin

6. **Common Name:**
Dental LT Clear V2 Resin

7. **510(k) Number:**
K222061

8. **Product Classification and Regulations:**

Primary Product Code: MQC (Mouthguard, Prescription)
Regulation: Not subject to a Part 800 classification regulation
Risk Class- Unclassified

Secondary Product Codes: KMY (Positioner, Tooth, Preformed), DYT (Maintainer, Space Preformed, Orthodontic)

Panel:
Dental

9. **Predicate Devices:**
Primary Predicate Device: KeyPrint® KeySplint Hard™ (K203000)
Secondary Predicate Device: KeyPrint® KeySplint Soft™ (K183598)

10. **Description of Device:**
Dental LT Clear V2 Resin is a light-curable polymer-based resin designed for the fabrication of biocompatible, long-term use, removable dental and orthodontic appliances by additive manufacturing.

11. **Indication for Use:**
Dental Clear LT V2 Resin when utilized to print dental or orthodontic appliances such as occlusal splints, night guards, or mouth guards is indicated to treat patients diagnosed with Temporomandibular Joint Disorders (TMD) and/or Bruxism, respectively.

12. **Summary of the non-clinical testing data**
Dental LT Clear V2 Resin meets the applicable standardized testing requirements for orthodontic materials. Table 1 summarizes the non-clinical testing data that was submitted, referenced, or relied on to demonstrate the substantial equivalence of the subject device, and whose performance meets the requirements of its pre-defined acceptance criteria.

Table 1: Summary the Non-Clinical Testing Data of Subject Device

Technological / Performance Characteristic	**Test Method**	**Acceptance Criteria**	**Post Cured Results**
Flexural modulus	*ASTM D790-17*	≧ 1 GPa	≥ 2000 MPa
Ultimate tensile strength	*ASTM D638-14*	≧ 35 MPa	≥ 50 MPa
Elongation	*ASTM D638-14*	≧ 0.8 %	≥ 10%
Hardness Shore D	*ASTM D2240-15*	*Compliant to ASTM D2240-15*	78D
Water Sorption	*ISO 20795-2*	<32 µg/mm^3	28 ug/mm3
Water Solubility	*ISO 20795-2*	<5 µg/mm^3	1 ug/mm3

13. **Biocompatibility:**
Dental LT Clear Resin (V2) has been 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 endpoints evaluated included: physical and chemical information, cytotoxicity, sensitization, irritation, acute systemic toxicity, sub-acute toxicity, sub-chronic toxicity, chronic toxicity, implantation and genotoxicity. The results of an independent biological risk assessment and endpoint testing confirmed biocompatibility. Dental LT Clear V2 is considered to meet the requirements of *ISO 10993-1:2018* and *ISO 7405:2018*, for a surface device that has long term (> 30 day) contact with mucosal membrane.

14. **Substantial Equivalence:**
Formlabs Ohio, Inc., submits that the Dental LT Clear V2 Resin is equivalent to the identified predicate devices KeyPrint® KeySplint Hard™ (cleared in K203000) and KeyPrint® KeySplint Soft™ (cleared in K183598) in multiple facets. After an exhaustive analysis of the subject Formlabs device and the predicate devices, Formlabs proffers that Dental LT Clear V2 Resin is substantially equivalent to the predicate devices with respect to the following:

• Product Code
• Indications for Use
• Device Design & User Interface
• Materials of Composition and Chemical Characterization
• Manufacturing Technology and Operating Principle
• Mechanical Properties and Performance Similarities
• Biocompatibility
• Patient Use and Reusability
• Removability

Comparison of the Indications for Use between the subject device and predicate devices:
The predicates KeyPrint® KeySplint HardTM and KeyPrint® KeySplint Soft™ are indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers. Dental LT Clear V2 Resin is utilized to print the same appliances as the predicates i.e., an occlusal splint, mouth guard, or night guard. Formlabs provides additional information about the medical conditions in which these appliances are widely indicated for treatment purposes in our indications for use statement.

Comparison of technological characteristics between the subject device and identified predicates:
The predicate devices and the subject device have comparable physical properties of elongation (complying to ASTM D638), flexural strength and flexural modulus (complying to *ASTM D790*), and hardness shore D (complying to *ASTM D2240*). All devices meet the applicable standardized testing requirements for orthodontic materials.
Notedly, the values for mechanical properties including flexural strength, flexural modulus, elongation and water solubility of the subject device were found to be falling in the range between the two 510(k) cleared predicates intended for similar indication for use.
Dental LT Clear V2 Resin and both the predicate devices complied to *ISO 20795* for testing Water sorption and values of the subject device for this testing are found to be greater than the predicate. Since the subject device along with the predicate fall between the acceptable ranges of the recognized standard, we can reasonably assume that any noted differences would not be cause for an NSE (not substantially equivalent) determination.

Table 2 presents a side-by-side comparison between the subject device and the identified predicate devices.

Table 2: Comparison of Technological Characteristics Between the Subject Device and Identified Predicates

Device Characteristic	**Dental LT Clear V2 Resin (Subject Device)**	**KeySplint Hard (Predicate Device)**	**KeySplint Soft (Secondary Predicate)**

Mechanical Properties and Performance[1]	Flexural Strength *(ASTM D790):* 84 MPa Flexural modulus *(ASTM D790-15):* 2300 MPa Elongation (*ASTM D638-10*): 12% Hardness Shore D (*ASTM D2240-15*): 78D Water Sorption (*ISO 20795-2*): 28 µg/mm3 Water Solubility (*ISO 20795-2*): 1 ug/mm3	Flexural Strength *(ASTM D790):* 100-110 MPa Flexural Modulus (*ASTM D790*): 2300-2400 MPa Elongation at Break (*ASTM D638*): 9% Shore D Hardness (*ASTM D2240*): 89D Water Sorption (*ISO 20795-2):* 18 µg/mm3 Water Solubility (*ISO 20795-2*): 0.1 ug/mm3	Flexural Strength *(ASTM D790):* 44–47 MPa Flexural Modulus (*ASTM D790*): 1,100–1,400 MPa Elongation at Break (*ASTM D638-05*): > 110% Shore D Hardness (*ASTM D2240*): 80–85 Water Sorption (*ISO 20795-2*): < 18 ug/mm3 Water Solubility (*ISO 20795-2*): < 4.8 ug/mm3

[1] Data for predicate devices referenced from publicly available Technical Data Sheet by KeySplint

Conclusion

As presented in this 510k summary, Formlabs deems its medical device Dental LT Clear V2 Resin to be substantially equivalent to the declared predicate devices. Both predicate devices and subject device are used in the fabrication of dental appliances that are typically customized to a patient's specific needs. It is reasonable to assume that any noted differences would not be cause for an NSE (not substantially equivalent) determination.