April 9, 2021

Mycone Dental Supply Co. Inc. (DBA Keystone Industries)
Diamond Bynum
Regulatory Affairs Associate
480 S. Democrat Road
Gibbstown, New Jersey 08027

Re: K203000
Trade/Device Name: KeyPrint KeySplint Hard
Regulatory Class: Unclassified
Product Code: MQC, KMY, EBI
Dated: September 30, 2020
Received: October 1, 2020

Dear Diamond Bynum:

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 Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

K203000

Indications for Use

***Device Name*:** KeyPrint® KeySplint Hard™

Indications for Use:
The KeyPrint® KeySplint Hard™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers.

Prescription Use X AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K203000

510(k) Summary
Pursuant to 21 CFR 807.92

Contact: Diamond Bynum
Keystone Industries
Regulatory Affairs Associate

Company Address: Mycone Dental Supply Co. Inc.
(DBA Keystone Industries)
480 S. Democrat Road
Gibbstown, NJ 08027
Phone: 1.800.333.3131
Fax: (856) 224-9444

Date Prepared/ Updated: April 02, 2021

Trade or Proprietary Name: KeyPrint® KeySplint Hard™

Classification Name: Mouthguard, Unclassified
Positioner, 872.5525

Common Name(s): Mouthguard
Positioner
Resin

Predicate Devices: Primary Predicate: KeyPrint® KeySplint Soft™ – K183598

Secondary Predicate: Whip Mix VeriSplint- K190107

Reference Predicate: Dentsply Mouthguard and Aligner – K062828

Device Description:
KeyPrint® KeySplint Hard™ material is a UV-curable methacrylate-based resin, intended to be used by trained dental professionals for the 3D printing of various biocompatible dental devices such as mouthguards, nightguards, splints, repositioners, and retainers. The printing of these devices is carried out using DLP printers utilizing pre-specified wavelengths. Each material is indicated for the fabrication of orthodontic and other dental appliances. Each material is recommended for the construction of

specific Class I and II dental devices and appliances. In most cases, the devices are 3D printed to create custom devices or appliances.

Indications for Use:
The KeyPrint® KeySplint Hard™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints, repositioners and retainers.

Performance Testing:
The predicate devices underwent physical property testing to determine product performance regarding flexibility, strength, durability, and the kinetic interaction with water. Samples made from Keyprint® KeySplint Hard™ underwent the same physical property testing and met all the requirements of each standard test performed. Additive manufacturing testing has been conducted per FDA Guidance on Additive manufacturing to demonstrate repeatability, physical properties, build orientation, and validation of system.

Biocompatibility:
Independent testing performed by Nelson Labs confirm Keyprint® KeySplint Hard™ meets the requirements for oral device biocompatibility.

Predicate Difference Discussion

KeyPrint® KeySplint Hard™ had the same physical property tests performed as that of the primary & secondary predicates. All results were similar to that of the predicates with no noticeable differences.

KeyPrint® KeySplint Hard™ is similar to our primary and secondary predicates in material processing. All resins are manufactured using very similar components and are processed into the final device using 3D printing and light curable polymerization. A difference between KeyPrint® KeySplint Hard™ and the primary predicate is identified in the formulation and final specifications. The formulation of Keyprint® KeySplint Soft ® was modified to create a stronger device that safely and effectively expands the device indications to include tooth retainer or repositioner. The biocompatibility results, and physical property data for KeyPrint® KeySplint Hard™ determined this difference is not critical to safety and effectiveness. KeyPrint® KeySplint Hard™ and the primary and secondary predicate device meet the ISO and ASTM standardized testing requirements applicable to the intended use.

Our new device resin is also similar to our reference predicate with respect to product indications –both device resins are intended to be used to fabricate orthodontic and other dental appliances. Dentsply Mouthguard (K062828) and KeyPrint® KeySplint Hard™ material can be used to create custom made, removeable dental devices, as stated in the indications for use. Both devices meet the applicable ISO and ASTM standardized testing requirements for orthodontic materials.

Conclusion

KeyPrint® KeySplint Hard™ material is used for the fabrication of customized dental devices. All the ingredients found in KeyPrint® KeySplint Hard™ have been chosen for their safe and effective use in dental and other types of medical devices. Based on the physical performance and biocompatibility test results of the KeyPrint® KeySplint Hard™ material, it has been confirmed that this device meets all the necessary standards

to prove this material can be used safely and effectively for its intended uses. Keystone Industries also confirms that there have been no known adverse incidents related to our biocompatible 3D resins. Moreover, the process of using methacrylate-based materials has a well-established history of being utilized in restorative formulations and devices. Therefore, we believe that the prior use of these components found in many legally marketed devices and the data provided within our 510(k) supports the safety and effectiveness of KeyPrint® KeySplint Hard™ for the indicated uses.