March 18, 2025

Whip Mix Corporation
Meena Muniaswamy
Q/A Regulatory Manager
361 Farmington Avenue
Louisville, Kentucky 40209

Re: K241729
Trade/Device Name: Hard Splint & Thermo-Adaptive Splint
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: June 14, 2024
Received: June 14, 2024

Dear Meena Muniaswamy:

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,

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)*

K241729

Device Name

Hard Splint;
Thermo-Adaptive Splint

Indications for Use *(Describe)*

Hard Splint is a 3D print light curable resin for the fabrication of orthodontic and dental appliances such as splints, mouthguards, nightguards, repositioners and retainers.

Thermo-adaptive Splint is a 3D print light curable resin for the fabrication of thermo-flexible orthodontic and dental appliances such as splints, mouthguards, nightguards, repositioners and retainers.

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.

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510(k) #: K241729

510(k) Summary

Prepared on: 2025-02-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	WHIP MIX CORPORATION
Applicant Address	361 Farmington Avenue Louisville KY 40209 United States
Applicant Contact Telephone	502-634-5342
Applicant Contact	Mrs. Meena Muniaswamy
Applicant Contact Email	mmuniaswamy@whipmix.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hard Splint; Thermo-Adaptive Splint
Common Name	Splint
Classification Name	Un-Classified
Regulation Number	NA (MQC) and 21 CFR 872.5525 (KMY)
Product Code(s)	MQC, KMY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183598	KeyPrint KeySplint Soft	MQC
K190107	VeriSplint	MQC

Device Description Summary

21 CFR 807.92(a)(4)

Whip Mix Dental Resin is light cured resin that is provided in a plastic container, and it is a proprietary blend of ingredients that make a generative resin. When the system (which includes a scanner, design software, printer software, resin, 3D printer, and curing unit) are used in combination, the result is an additive manufactured orthodontic, thermo-flexible orthodontic, or dental appliances such as mouthguards, splint, nightguards, repositioners and retainers.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Hard Splint is a 3D print light curable resin for the fabrication of orthodontic and dental appliances such as splints, mouthguards, nightguards, repositioners and retainers.

Thermo-adaptive Splint is a 3D print light curable resin for the fabrication of orthodontic and dental appliances such as splints, mouthguards, nightguards, repositioners and retainers.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Yes, the indication for use is same as Predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

1. Comparison of technological characteristics with the predicate device.

The intended use, critical specifications, and additive manufacturing methods of the Hard Splint and Thermo-adaptive Splint are substantially equivalent to the predicate device, KeyPrint KeySplint Soft. Though the chemical composition of the predicate device differs from Whip Mix's resins, all fall into the same material category and are photocureable resins which are used in additive manufacturing.

Additionally, Whip Mix's resins are technologically similar to the reference device K190107, Whip Mix VeriSplint, which uses a photo-curable resin, similar design software and scanner, as well as the same type of printer software and 3D printer.

2. Substantial Equivalence Conclusion

Based on the similarities in product code, classifications, materials, technical features, and biocompatibility results, the new Whip Mix resins demonstrate substantial equivalence to the predicate device, KeyPrint KeySplint Soft.

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

1.Flexure properties -Whip Mix Internal Requirements
2.Fracture properties -ISO 20795-2
3.Water Sorption and Solubility -ISO 20795-2 & Whip Mix Internal Requirements
4.Residual Methyl Methacrylate- ISO 20795-2

N/A

The Hard Splint and Thermo-Adaptive Splint are biocompatible, similar to the predicate device, and have equivalent or better mechanical testing performance compared to the predicate device.