July 10, 2019

Whip Mix Corporation
John Waters
Quality Assurance Manager
361 Farmington Avenue
Louisville, Kentucky 40217

Re: K190107
Trade/Device Name: VeriSplint
Regulatory Class: Unclassified
Product Code: MQC, EBI
Dated: April 09, 2019
Received: April 11, 2019

Dear John Waters:

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,

for Srinivas Nandkumar, Ph.D.
Acting 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

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Phone: (502)637-1451 ● Fax(502)634-4512 ● www.whipmix.com

4. Indications for Use

Indications for Use

510(k) Number (if known):K190107

Indications for Use:

Whip Mix VeriSplint is a light-cured resin. It is a polymer used to create removable structures for therapeutic restorations i.e., bite guards/splints and occlusal night guards/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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5. 510K Summary K190107

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92

Date Prepared: April 9, 2019

5.1 APPLICANT

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5.2 SUBMITTER and CONTACT

John P. Waters
Quality Assurance Manager
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DATE: Jun 26, 2019

5.3 DEVICE NAME

VeriSplint

5.4 COMMON OR USUAL NAME AND CLASSIFICATION

Mouthguard, Prescription
Regulation Number: **Un-classified**
Product Code: **MQC**
Reference Product Code: **EBI**
Classification: **Dental**

5.5 PREDICATE DEVICE INFORMATION

Whip Mix claims K150432, Idodentine Dental Polymer Blank as the primary predicate. K162572, Nextdent Denture/EDenture is our reference predicate.

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5.6 DEVICE DESCRIPTION

The VeriSplint ®OS system is a combination of a scanner, resin, 3D printer, and curing unit. The system components work together to manufacture a splint/bite guard. The additive manufactured appliance is part of a photo-cured product family that is a combination of methacrylate and acrylate resins. In general, the products in this family are composed of a 3-component methacrylic and acrylic system, polymerized via photo initiators in a 3D printer setting. The material is an alternative to traditional heat cured and auto polymerizing resins.

5.7 INDICATIONS FOR USE

Whip Mix VeriSplint is a light-cured resin. It is a polymer used to create removable structures for therapeutic restorations i.e., bite guards/splints and occlusal night guards/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.

5.8 SUBSTANTIAL EQUIVALENCE WITH PREDICATE DEVICES

Requirement	Whip Mix new device	Primary Predicate	Reference Predicate
Class	Un-classified	II	II
510K number	K190107	K150432	K162572
Device Name	VeriSplint	Idodentine Disc, Idodentine Block	Nextdent Denture, E-Denture
Device Classification Name	Mouthguard, Prescription	Crown and Bridge, Temporary, Resin	Resin, Denture, Relining, Repairing, Rebasing
Classification Code	MQC, EBI	EBG, EBI, MQC	EBI
Ingredient	Light-cured Resin	Hot cured PMMA	Light-cured Resin
Manufacturing Technology	Additive	Heat cured	Additive
Flexural Strength ≥ 50 MPa	> 100 MPa	90 MPa	Not provided
Flexural Modulus ≥ MPa 1500	> 2500 MPa	Not provided	Not provided
Regards to sterility	Non Sterile	Non Sterile	Not provided
Water solubility ≤ 5µg/mm³	< 1 µg/mm³	0.0000 mg/mm³	Not provided
Water Sorption ≤ 32µg/mm³	29 µg/mm³	0.023 mg/mm³	Not provided
Indications for Use	Whip Mix VeriSplint is a light-cured resin. It is an orthodontic base polymer used to create removable structures for therapeutic restorations like bite guards/splints and occlusal night guards/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.	Acrylic polymer blank particularly suitable for making removable or temporary dental structures such as crowns and bridges using milling technology using CAD/CAM. Indications -Temporary anterior and posterior crowns - Temporary anterior and posterior bridges with up to two adjacent pontics - Implant supported temporary restorations Maximum	NextDent Denture / E-Denture is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures.

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Requirement	Whip Mix new device	Primary Predicate	Reference Predicate
		recommended usage period: 12 months - Removable structures for dentures (dental bases) - Removable structures for therapeutic restorations (bite splints or occlusal splints)	
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Residual monomer content ≤ 5%	≤ 0.10 %	1.4%	Not provided

5.9 PERFORMANCE TESTING

The predicate performed tests for Flexural Strength, Flexural Modulus, Water Solubility, Water Sorption, Biocompatibility, and Residual monomer content. Whip Mix performed these tests as well and all met the requirements of ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers.

5.10 BIOCOMPATIBILITY

Test results confirm Verisplint meets all the requirements for biocompatibility.

5.11 PREDICATE DIFFERENCE DISCUSSION

Whip Mix performed testing as that of the predicate. Flexural Strength, Flexural Modulus, Water Solubility, Water Sorbtion, residual monomer, and all results were similar to that of the predicate.

Our new device is similar to our main predicate K150432. They both have the product code MQC. Both IFU's state they can be used for removable structures for therapeutic restorations (bite splints or occlusal splints). Both meet the requirements of ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers, and are biocompatible.

Our new device is also similar to our reference predicate K162572. Both have product code EBI. Both are light-cured resins used in the additive manufacturing process and use a resin, scanner, printer, and curing unit in the additive manufacturing process. Both comply with ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers, contact the mucosal membrane for > 30 days, and both are biocompatible.

5.12 CONCLUSION

The VeriSplint system is very similar to both predicates and demonstrate substantial equivalence to Union Dental K150432, and Vertex-Dental K162572. An analysis for our device compared to the predicates show Verisplint and the Idodentine Disc meet the requirements of ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers. All three devices share the same product code, meet or exceed the minimum strength requirements, and all three are biocompatible. Any differences between Whip Mix new device and the predicates are minimal and present no new risks.