April 27, 2023

Innovative Product Brands, Inc.
Shane Nielsen
Chief Executive Officer
7045 Palm Avenue
Highland, California 92346

Re: K223892
Trade/Device Name: DentMix VPS Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: February 7, 2023
Received: February 7, 2023

Dear Shane Nielsen:

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)*
K223892

Device Name
DentMix VPS Impression Material

Indications for Use *(Describe)*
DentMix VPS Impression Material is intended for use with all crown and bridge, occlusal and implant impression techniques to reproduce the structure of a patient's teeth and gums.

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."

K223892
510(k) Summary

Submitter:
IPB Inc
7045 Palm Avenue
Highland, CA 92346

Contact Person:
Shane Nielsen
President / CEO
909-864-7477

Date Summary Prepared:
(Revised per FDA request) April 2023

Device Name
Trade Name: DentMix VPS Impression Material
Common Name: Dental Impression Material
Device Classification: Class II
Classification Product Code: ELW
Classification Name: Material, Impression, per 21 CFR 872.3660

Predicate Device
ElementsTM

Description of Device
DentMix VPS Impression Material is an addition-reaction base/catalyst polyvinylsiloxane dental impression material intended as an alternative to traditional alginate materials. It is available in regular set and fast set. Both are available in light body, regular body/monophase and heavy body.

Indications for Use
DentMix VPS Impression Material is intended for use with all crown and bridge, occlusal and implant impression techniques to reproduce the structure of a patient's teeth and gums.

IPB Inc
Innovative Product Brands

Comparison of Technological Characteristics

Descriptive Information	Subject Device DentMix VPS Impression Material (K223892)	Predicate Device Elements (K151150)	Summary
Indications for Use	DentMix VPS Impression Material is intended for use with all crown and bridge, occlusal and implant impression techniques to reproduce the structure of a patient's teeth and gums.	Elements™ is intended for use with all crown and bridge, occlusal and implant impression techniques to reproduce the structure of a patient's teeth and gums.	The indications for use of the subject and predicate devices are intended for use with all crown and bridge, occlusal and implant impression techniques to reproduce the structure of a patient's teeth and gums.
Composition of Materials	Vinyl Polysiloxane Filler Pigments	Vinyl Polysiloxane Filler Pigments	The composition of the subjective and predicate devices are the same.
Mode of Use	1. Light body (Type 3) A low viscosity impression material used to capture extraordinary subgingival details. 2. Regular body/Monophase (Type 2) A medium viscosity monophase impression material used in single step impression procedures. 3. Heavy body (Type 1) A heavy body impression material used as base in two-step heavy-wash applications.	1. Light body (Type 3) A low viscosity impression material used to capture extraordinary subgingival details. 2. Regular body/Monophase (Type 2) A medium viscosity monophase impression material used in single step impression procedures. 3. Heavy body (Type 1) A heavy body impression material used as base in two-step heavy-wash applications.	The mode of use of the subjective and predicate devices are the same.
FDA-Recognized Standards	ISO 4823-2015	ISO 4823-2015	Claims are the same

IPB Inc
Innovative Product Brands

Comparison of Testing

Test Method	Dentimix VPS Impression Material (K223892)			Elements TM (K151150)		
	Heavy Body	Monophase	Light Body	Heavy Body	Monophase	Light Body
Mixing Time	N/A	N/A	N/A	N/A	N/A	N/A
Consistency	32mm	35mm	40mm	31mm	35mm	39mm
Working Time (Regular Set)	2'34"	2'12"	2'37"	2'30"	2'30"	2'30"
Working Time (Fast Set)	1'16"	1'23"	1'21"	1'30"	1'30"	1'30"
Detail Reproduction	PASS	PASS	PASS	PASS	PASS	PASS
Linear Dimensional Change	0.14% (0.01)	0.05% (0.02)	0.08% (0.02)	0.14% (0.01)	0.05% (0.02)	0.08% (0.02)
Compatibility with Gypsum	PASS	PASS	PASS	PASS	PASS	PASS
Elastic Recovery	99.1 (.2)	99.1 (.3)	98.9 (.1)	99.7 (0.1)	99.6 (0.3)	99.8 (0.1)
Strain-In-Compression	2.54 (.8)	3.61 (.4)	5.91 (1.6)	2.85 (0.1)	3.67 (0.13)	4.93 (0.1)

Conclusion:

Dentimix VPS Impression Material is substantially equivalent to the predicate device Elements TM (K151150) in terms of physical properties.