



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 28, 2015

Pac-Dent International, Inc.
Ms. Wenying Zhu
Materials Engineer
21038 Commerce Point Drive
Walnut, CA 91789

Re: K151150
Trade/Device Name: Elements™
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Codes: ELW
Dated: April 24, 2015
Received: April 30, 2015

Dear Ms. Zhu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure



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Section III

Indications for Use Statement

510(k) Number (if known): K151150

Device Name: Elements[™]

Indications for Use:

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.

Prescription Use X OR Over-The-Counter Use



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Section IV

510(k) Summary

Submitter:

Pac-Dent International, Inc.
670 Endeavor Circle
Brea, CA 92821

Contact Person:

Wenyong Zhu
Materials Engineer
909-839-0888 ext.111

Date Summary Prepared:

July 2015

Device Name

Trade Name: Elements™

Common Name: Dental Impression Material

Device Classification: Class II

Classification Product Code: ELW

Classification Name: Material, Impression, per 21 CFR 872.3660

Predicate Device

Take 1 (K091613)

Description of Device

Elements™ 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

Elements™ is intended for use with all crown and bridge, occlusal and implant impression



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techniques to reproduce the structure of a patient's teeth and gums.

Summary of Biocompatibility Tests

The biocompatibility of Elements[™] was found to be substantially equivalent to the predicate based on a risk assessment done per ISO 10993-1 and the identification of legally marketed predicate devices for all ingredients in the chemical composition.

Comparison of Technological Characteristics

Descriptive Information	Subject Device Elements [™]	Predicate Device Take 1 (K091613)	Summary
Indications for Use	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.	Take 1 is an addition-cure vinly polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.	The indications for use of the subject and predicate devices is to reproduce the structure of a patient's teeth and gums, including but not limited to the applications listed in the indications for use.
Composition of Materials	Vinly polysiloxane Filler Pigments	Vinly 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	1. Take 1 Light body/Regular body wash: A very hydrophilic impression material used in heavy/wash or putty/wash impression procedures and capable of capturing extraordinary subgingival details. It is used in crown and bridge and all	The nomenclature is different between the subjective and predicate devices. According to the description and bench test result, subjective device's



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	<p>monophase impression material used in single step impression procedures.</p> <p>3. Heavy body (Type 1) A heavy body impression material used as base in two-step heavy-wash applications.</p>	<p>high precision applications.</p> <p>2. Take 1 Medium body: A medium viscosity monophase impression material with superior mechanical strength used in single step impression procedures such as mouth guards, night guards, orthodontic, and edentulous applications.</p> <p>3. Take 1 Tray (heavy body) A heavy body impression material combining strength, elasticity and dimensional stability to deliver the most accurate impressions. It is used in two-step heavy-wash applications such as for crown and bridge procedures.</p>	<p>light body is comparable to predicate device's light body/regular body wash, regular body/monophase is comparable to medium body and heavy body is comparable to tray. The classification of the subjective device is also complied with ISO 4823-2000 (Type 1-Type 3).</p>
FDA-Recognized Standards	ISO 4823-2000	ISO 4823-2000	Claims are the same

Comparison of physical properties

Test Method ISO 4823-2000	Elements™			Take 1 (K091613)		
	Heavy body	Regular body/Monophase	Light body	Tray (heavy body)	Medium body	Light body/Regular body wash
Detail Reproduction	PASS	PASS	PASS	PASS	PASS	PASS
Linear Dimensional Change	0.14% (0.01)	0.05% (0.02)	0.08% (0.02)	0.03% (0.01)	0.07% (0.01)	0.07% (0.01)
Compatibility with Gypsum	PASS	PASS	PASS	PASS	PASS	PASS
Elastic Recovery	99.7 (0.1)	99.6 (0.3)	99.8 (0.1)	99.45 (0.1)	99.65 (0.1)	99.84 (0.1)
Strain-In-Compression	2.85 (0.1)	3.67 (0.13)	4.93 (0.1)	2.92 (0.25)	3.4 (0.15)	5.4 (0.15)



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Substantial Equivalence

In summary, this submission demonstrates that Elements™ is substantially equivalent to the identified predicated product for its intended use and technological characteristics. Non clinical performance testing per ISO 4823-2000 substantiates equivalence in terms of detail reproduction, linear dimensional change, compatibility with gypsum, elastic recovery and strain in compression.

No clinical testing was performed.