DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Pac-dent International, Inc
Jack Li
Regulatory Affair Associate
670 Endeavor Circle
Brea, California 92821

October 20, 2017

Re: K162662
Trade/Device Name: GingiDent Gingival Retraction Paste
Regulation Number: 21 CFR
Regulation Name: (Not A Regulation) Retraction Cord
Regulatory Class: Unclassified
Product Code: MVL
Dated: September 6, 2017
Received: September 8, 2017

Dear Jack Li:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting 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): K162662

Device Name: GingiDent Gingival Retraction Paste

Indications for Use:

For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, taking an impression, cementation and cavity preparation.

Prescription Use X OR Over-The-Counter Use _____

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K162662

510(k) Summary

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

Contact Person:
Jiahe Li
Regulatory Affair Associate
Tel: 909-839-0888 ext.109

Date Summary Prepared:
October 16th, 2017

DEVICE NAME

TRADE NAME: GingiDent Gingival Retraction Paste

COMMON NAME: Retraction Cord

DEVICE CLASSIFICATION: Unclassified

CLASSIFICATION PRODUCT CODE: MVL

PREDICATE DEVICE

Primary predicate device: Expa-syl - Sybron Dental Specialties, Inc. - K050180
Reference predicate device: Traxodent - Premier Dental Products Co - K083695

DESCRIPTION OF DEVICE

GingiDent gingival retraction paste is an astringent formulated to provide gingival retraction and

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hemostasis. GingiDent gingival retraction paste contains Aluminum Chloride and is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures. This product is a blue-green paste developed exclusively for transient surgically invasive use in the oral cavity. The paste contains Aluminum Chloride Hexahydrate in a water-based clay inert carrier.

INDICATIONS FOR USE

For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, taking an impression, cementation and cavity preparation.

Non-Clinical Tests

This 510(k) submission includes data from bench testing to evaluate the performance of the subject device compared to predicate devices. Tests performed include measurement of pH value, viscosity and Aluminum Chloride Hexahydrate concentration.

Bench Tests Result Summary

Manufacturer	Pac-Dent	Sybron Dental Specialties, Inc.	Premier Dental Products
Product	GingiDent	Expa-syl	Traxodent
Aluminum Chloride Hexahydrate	16.42%	15.80%	21.76%
pH	3.22	3.47	2.99
Viscosity (cP)	995,000	>1 million	763,000

Conclusion of Bench Tests

GingiDent Gingival Retraction Paste is substantially equivalent to the predicate devices Expa-syl and Traxodent in terms of active ingredients and pH value. While the two predicate devices show big differences in their viscosity measurements comparatively, the difference in viscosity does not affect the effectiveness (the active ingredient is Aluminum Chloride Hexahydrate). It is up to the manufacturer to decide the best viscosity for its formulation in consideration of stability, handling and customer feedback. Therefore, there is sufficient evidence to conclude that the difference in viscosity does not affect the effectiveness of the subject device for its intended use, which has a viscosity level that falls between that of the two predicate devices.

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Summary of Biocompatibility Tests

Biocompatibility tests in accordance with ISO10993 have been performed, including skin sensitivity test and oral mucosa irritation tests in hamster. The results of the tests show no evidence of causing skin sensitization and oral mucosa irritation.

Summary of Stability Tests

In accordance with the requirements of ISO 28399-2011, the accelerated stability of retraction paste with high viscosity was investigated over the time of incubation in an oven at 50 °C and 60 °C. At a predetermined time point, the retraction paste was evaluated in terms of AlCl3·6H2O concentration, pH value, extrusion force, weight loss, and etc. Based on the results obtained, the shelf life of the retraction paste for room temperature storage was estimated to be 2.8 years, which is substantially equivalent to the predicate devices.

Clinical Performance Test

No clinical testing was provided.

Comparison of Technological Characteristics

Descriptive Information	**Subject Device** GingiDent Gingival Retraction Paste	**Primary Predicate Device** Expa-syl (K050180)	**Reference Device** Traxodent (K083695)	**Substantial Equivalence**
Indications for Use	**GingiDent Gingival Retraction Paste:** For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to taking an impression, cementation, cavity preparation. **K050180:** Expa-syl is a paste containing aluminum chloride which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.			Yes

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<table>
<tr><td></td><td colspan="3">K083695: Traxodent has been specifically formulated to provide gingival retraction and hemostasis. It is intended for use prior to taking an impression, for cavity preparation or wherever hemostasis and retraction is required.</td><td></td></tr>
<tr><td></td><td colspan="3">Comments: All three devices are used for gingival retraction and hemostasis as required during dental procedures. The key words are the same. The small differences in the language used do not impact the substantial equivalence of the subject device to the predicate device in terms of Indications for Use.</td><td></td></tr>
<tr><td rowspan="3">Composition of Materials</td><td colspan="3">Same:
Aluminum Chloride Hexahydrate in a water-based kaolin paste.</td><td rowspan="3">Yes</td></tr>
<tr><td>Difference:
Dye
(blue-green)
Propylene
Glycol，
Peppermint</td><td>Difference:
Dye
(grey-green)</td><td>Difference:
Dye (yellow)</td></tr>
<tr><td colspan="3">Comments: The subject device and predicate devices comprise of the same main ingredients: aluminum chloride hexahydrate, kaolin and water. The percentage of kaolin used in the subject device and main predicate device is comparable. The Propylene Glycol is an inactive ingredient used in subject device as a solvent. Peppermint is an inactive ingredient used in subject device as a flavor. The dye used in subject device is different but doesn’t impact the effectiveness and safety of the subject device.</td></tr>
<tr><td>Principles of Operation</td><td colspan="3">Same:
In the retraction process, light kaolin ensures the consistence of paste and its mechanical action while</td><td>Yes</td></tr>
</table>

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	and aluminum chloride enhances the hemostatic action.[1] DI water is used to dissolve the astringent agent and give a paste of the desired viscosity, texture and appearance.	
	Difference: None.	
	Comment: The principles of operation of the subject device are the same as the predicate devices.	
Physical Property	See previous section *Bench Tests Result Summary* for details.	Yes
	Comment: While the two predicate devices show big differences in their viscosity measurements comparatively, the difference in viscosity does not affect the effectiveness (the active ingredient is Aluminum Chloride Hexahydrate). It is up to the manufacturer to decide the best viscosity for its formulation in consideration of stability, handling and customer feedback. Therefore, there is sufficient evidence to conclude that the difference in viscosity does not affect the effectiveness of the subject device for its intended use, which has a viscosity level that falls between that of the two predicate devices.	
Device Classification & Product Code	**Same:** Device Classification: Unclassified product code: MVL	Yes

Conclusion

In summary, non-clinical performance testing demonstrates that GingiDent gingival retraction paste is substantially equivalent to the identified predicate products for its intended use.

[1] Dr. Ara Nazarian. (2007, September). Tissue Management with Expasyl; A Key to Restorative Success. *Dentaltown, 52.*