DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 24, 2015

Ultradent Products, Inc.
Corey Jaseph, MS, RAC
Regulatory Affairs Manager
505 West 10200 South
South Jordan, Utah 84095

Re: K152064
Trade/Device Name: Astringedent Clear
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MVL
Dated: August 27, 2015
Received: August 28, 2015

Dear Ms. Jaseph:

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" (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 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 yours,

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

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
Est. Reg. No. 1718912

Section 4: Indications For Use Form FDA-3881

Ultradent Products, Inc.
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South Jordan, UT 84095
Est. Reg. No. 1718912

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Astringedent Clear

Indications for Use *(Describe)*
Astringedent Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The solution facilitates the insertion of the cord into the sulcus.

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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Section 5: Special 510(k) Summary

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

I. Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Ms. Corey Jaseph, MS, RAC
Title:	Regulatory Affairs Manager
Telephone:	800-552-5512 x4420, 801-553-4420
FAX:	801-553-4609

Date Summary Prepared:	23 July 2015

II. Name of the Device

Trade Name:	Astringedent Clear
Common Name:	Retraction Cord
Device Classification:	Unclassified
Classification Product Code:	MVL
Regulation No.	None (pre-amendment)

III. Predicate Device:

Astringedent Clear is substantially equivalent to Viscostat Clear (K123215), also manufactured by Ultradent Products, Inc.

IV. Device Description:

Astringedent Clear is a 12% w/w aluminum chloride solution in a non-viscous, aqueous vehicle. It leaves no residue or stain, making it ideal for use in the esthetic zone. It is packaged in two configurations: 30 mL IndiSpense, 30 mL bottle packaged with retraction cord. It is used both for obtaining clear dental impressions, as well as operative dental procedures requiring hemostasis and fluid control.

V. Statement of intended use:

Astringedent Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The solution facilitate the insertion of the cord into the sulcus.

VI. Comparison of technological characteristics

Astringedent Clear and Viscostat Clear have similar technological characteristics:

Table 5-1: Substantial equivalence comparison

Characteristic	Predicate: Viscostat Clear (K123215)	Astringedent Clear
Intended Use	Viscostat Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The gel facilitates the insertion of the cord into the sulcus.	Astringedent Clear is intended for sulcus retraction prior to impression making and to control bleeding and gingival oozing in restorative and operative dentistry used with gingival retraction cord and/or the Dento Infusor. The solution facilitates the insertion of the cord into the sulcus.
Intended user	Dental professional	Dental professional
Chemical Characteristics	Aluminum chloride gel	Aluminum chloride solution
Primary Container	30 ml Indispense container, 1.2 mL syringe	30 ml Indispense container, 30 ml bottle packaged with retraction cord
Physical properties	Clear gel	Clear solution
Compatibility	Does not adversely affect bond strength when used as directed	Does not adversely affect bond strength when used as directed
Time in mouth	1 – 3 minutes	1 – 3 minutes
Viscosity	Viscous gel	Nonviscous solution
Biocompatibility	Device demonstrated to have low cytotoxicity per ISO 10993-5, ISO 7405	Device not tested (same active ingredient, similar formulation)

Astringdent Clear has been tested for aluminum chloride content, wettability, effect on bonding (shear bond strength), and stability, and met all design input requirements. Astringedent Clear has the same indications for use, intended user, active ingredient,

same/similar delivery systems (predicate and modification are delivered in a polypropylene 30 mL Indispense syringe, and the modification is also available in a 30 mL glass bottle packaged with retraction cord), and use time. Astringedent Clear is less viscous than Viscostat Clear, which is intended to allow it to more easily and quickly soak into retraction cord for routine use in ensuring and maintaining hemostasis and sulcular fluid control during retraction.

Both work by using aluminum chloride to cause a contraction of the oral mucosal tissues, resulting in control of routine bleeding and sulcular fluid. Aluminum chloride has been used for many years in this manner for obtaining clear dental impressions and operative dental procedures requiring hemostasis and fluid control, as described in peer-reviewed literature.

Based on the results of design verification testing as outlined above, Ultradent has determined that Astringedent Clear is substantially equivalent to Viscostat Clear.