K123215

FEB 0 5 2013

Section 5: 510(k) Summary

This summary of the Traditional 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:	Karen Kakunes, RN
Title:	Sr. Regulatory Affairs Associate
Telephone:	800-552-5512 x4420, 801-553-4366
FAX:	801-553-4609
Date Summary Prepared:	26 Sep 2012

II. Name of the Device

Trade Name:	ViscoStat® Clear
Common Name:	Cord, Retraction
Device Classification:	Unclassified
Classification Product Code:	MVL
Regulation No.	None

III. Legally Marketed Predicate Devices to Which Equivalence is Claimed

ViscoStat® Clear is substantially equivalent to Racegel™ (K093711), manufactured by Septodont, which is cleared under dental device product code MVL (cord, retraction). ViscoStat Clear is substantially similar to the predicate device in Indications for Use, chemical composition, mechanical and physical properties and method of application and removal.

IV. Device Description:

ViscoStat Clear is a 25% Aluminum Chloride gel in a viscous, aqueous vehicle which leaves no residue or stain and makes it ideal for use in the esthetic zone. The product is contained within a 30mL or 1.2mL plastic syringe. The 30mL syringe is a bulk container and, prior to application, will be dispensed into provided, empty 1.2mL plastic syringe

for delivery to the patient. Dento-Infusor application tips are included and are used to apply the product to the prepared area.

V. Statement of 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.

VI. Comparison of technological characteristics

Table 5-1: Substantial equivalence comparison

Characteristic	Comparison Product (Racegel™ K093711)	ViscoStat Clear
Intended Use	Racegel is a gel containing aluminum chloride which is intended for sulcus retraction prior to impression taking; control of bleeding and gingival oozing, particularly in restorative dentistry; and, if using a gingival retraction cord, the gel facilitates the insertion of the cord into the sulcus	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.
Intended user	Dental professional	Dental professional
Chemical Characteristics	Aluminum chloride gel	Aluminum chloride gel
Recommended contact time	2 minutes	1-3 minutes
Delivery system	Pre-filled syringe with applicator tip	1.2ml pre-filled syringe with applicator tip, 30ml Indispense syringe with 1.2ml empty syringe and applicator tip
Physical properties	Orange, odorless gel	Clear gel

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	24 month shelf life	42 month shelf life
Biocompatibility	Acute oral toxicity Sensitization Oral Mucosa Irritation Cytotoxicity	Cytotoxicity
Functional Testing	Unknown	Aluminum Chloride content Effect on Shear Bond Strength Blood coagulation

ViscoStat Clear is a similar material used in the same way by the same types of users as the identified predicate device Racegel, introducing no new safety or efficacy questions. Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. In-house comparison testing has been performed on ViscoStat Clear and the predicate device, Racegel. The data supports the functionality of ViscoStat Clear. In summary, this submission demonstrates that ViscoStat Clear is safe and effective and performs equivalently to the identified predicates for its intended use.

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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

February 5, 2013

Ms. Karen Kakunes, RN
Senior Regulatory Affairs Associate
Ultradent Products, Incorporated
505 West 10200 South
SOUTH JORDAN UT 84095

Re: K123215
Trade/Device Name: ViscoStat® Clear
Regulation Number: Unclassified
Regulation Name: Cord, Retraction
Regulatory Class: Unclassified
Product Code: MVL
Dated: September 26, 2012
Received: November 7, 2012

Dear Ms. Kakunes:

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.

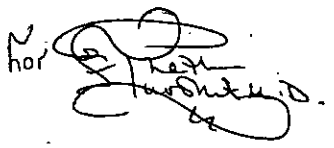
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Statement of Indications for Use

510(k) Number (if known): K123215

Device Name: ViscoStat Clear

Indications for 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.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.30 11:55:56 -05'00'

(Posted November 13, 2003)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123215