K113839

APR 12 2012

510(k) SUMMARY

Submitter:	Parkell, Inc. 300 Executive Drive Edgewood, NY 11717 TEL: 631-249-1134 FAX: 631-249-1242
Contact:	Daniel R. Schechter, Esq. VP, Regulatory Affairs Parkell, Inc. 300 Executive Drive Edgewood, NY 11717
Submission Date:	16 December 2011
Trade Name:	RETRACT
Common Name:	Gingival Retraction/Hemostatic Paste
Classification Name:	None
Classification Product Code:	MVL
Predicate Devices:	TRAXODENT (K083695), EXPASYL (K050180), RACEGEL (K093711)
Device Description:	RETRACT is a dental product capable of controlling gingival bleeding, temporarily displacing the marginal gingiva and temporarily drying the gingival sulcus around a tooth. The paste allows the dental clinician to perform operative procedures without interference from moisture or excess soft tissue. RETRACT is supplied in 0.5 ml syringes with a hand plunger, intra-oral tips, Instructions for Use & MSDS.
Intended Use:	RETRACT is a paste containing aluminum chloride which is used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as dental impressions.
Tech. Characteristics:	RETRIEVE gingival retraction/hemostatic paste is a single part paste and is typically supplied in a single-barrel syringe. The paste is dispensed by hand into and around the sulcular area of a prepared tooth for retraction and hemostasis and is then easily washed away with water. The material is biocompatible based on the directed usage, the known material profiles, and the extensive usage history of the constituents. Other than the aluminum chloride, the remaining ingredients are all food grade (or better) materials.

Substantial Equivalence: Parkell's RETRACT gingival retraction/hemostatic paste has similar indications, principles of operation, and technological characteristics as the predicate devices. The minor differences in the device do not raise any new questions of safety or effectiveness. Thus, RETRACT is substantially equivalent to its predicate devices. For example, the three predicate devices contain aluminum chloride in concentrations ranging from 15% - 25%. RETRACT has approximately 22% aluminum chloride. In addition, RETRACT, TRAXODENT and EXPASYL all use clay or similar materials as the primary fillers/thickening agent in the mixture with aluminum chloride.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Daniel R. Schechter, Esq.
Vice President, Regulatory Affairs
Parkell, Inc.
300 Executive Drive
Edgewood, New York 11717

APR 12 2012

Re: K113839
Trade/Device Name: RETRACT Gingival Retraction/Hemostatic Paste
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MVL
Dated: March 20, 2012
Received: March 26, 2012

Dear Mr. Schechter:

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,

for

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: RETRACT Gingival Retraction/Hemostatic Paste

Indications for Use: K 113839

RETRACT is a paste containing aluminum chloride which is used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as dental impressions.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K113839