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

June 6, 2016

Steiner Laboratories
Gregory Steiner
CEO
1051 Olsen Street, Building 3611
Henderson, Nevada 89011

Re: K142130
Trade/Device Name: Oral Bond
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: May 5, 2016
Received: May 10, 2016

Dear Gregory Steiner:

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 yours,

Susan Runner DDS, MA

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

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)*
K142130

Device Name

Oral Bond

Indications for Use *(Describe)*

Oral Bond is indicated to be used as an adjunct to temporally assist in securing periodontal dressings.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K142130

510K Summary

SUBMITTED BY

Owner: Gregory Gene Steiner

CEO Steiner Biotechnology LLC

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Henderson, Nevada 89011 P 866 317 1348

Contact person: Gregory Gene Steiner (ggsteiner@steinerlabs.com)

Date of preparation 06/05/2016

This summary of 510k substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 872.3275. Oral Bond has the same active chemical compound as found in PeriAcryl and is being submitted as a dental cement.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Dental cement

Common/Usual Name: Dental cement

Proprietary Name: Oral Bond

Product Code: EMA

Panel: Dental

Regulation No. 21 CFR Part 872.3275

Device Class: Class II

PREDICATE DEVICE

The predicate device is PeriAcryl.

DEVICE DESCRIPTION

Oral Bond is a sterile, liquid dental cement containing a monomeric (2-octyl cyanoacrylate) formulation with a viscosity increasing agent, stabilizer, and colorant (D&C Violet #2 or D&C Yellow #10) . Oral Bond is supplied in a multiuse vial. The liquid is syrup-like in viscosity and polymerizes within seconds after contact with water.

INDICATIONS FOR USE: Oral Bond is indicated to be used as an adjunct to temporally assist in securing periodontal dressings.

WARNINGS AND PRECAUTIONS:

Oral Bond is a fast setting adhesive capable of adhering to most bodily tissue and many other materials, such as latex gloves and stainless steel. Inadvertent contact with any body tissue, and any surfaces or equipment that are not disposable or that cannot be readily cleaned with a solvent such as acetone should be avoided.

Polymerization of Oral Bond adhesive may be accelerated by water, saliva or fluids containing alcohol.

It is advised that protective eyewear be provided all patients to prevent Oral Bond coming in contact with the eye. Care must be taken that Oral Bond does not come I contact with the cornea of the eye or into the conjunctival sac where it could cause adhesions. If contact with the eye occurs, flush the eye copiously with saline or water. If residual adhesive remains, apply typical ophthalmic ointment to help loosen the bond and contact and ophthalmologist.

When applying Oral Bond position the patient so any runoff is absorbed by the surrounding cotton gauze. Prevent Oral Bond from flowing past the intended materials that are intended to be bonded.

Once the applicator tip is applied to the syringe express a small amount of Oral Bond outside of the patient's mouth in order to avoid an accidental excessive application of the material in the patient's oral cavity.

If unintended bonding of skin occurs, peel but do not pull the skin apart. Petroleum jelly or acetone may help loosen the bond. Other agents such as water or saline are not expected to immediately loosen the bond.

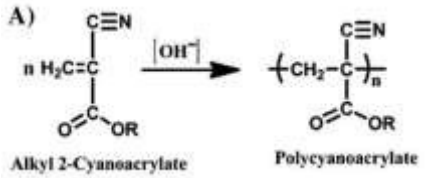
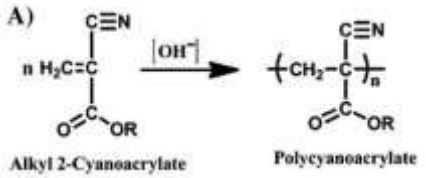
CONTRAINDICATIONS:

Do not use in patients with a known hypersensitivity to cyanoacrylate or formaldehyde. Oral Bond must not come in contact with the conjunctival sac since conglutination may occur.

Federal law restricts this device for sale on the order of a dentist.

PREDICATE DEVICE COMPARISON TABLE

	Oral Bond	PeriAcryl
510K	K142130	K071484
Intended use	Temporary dental adhesive	Temporary dental adhesive
Materials	2-octyl cyanoacrylate	Butyl/octyl cyanoacrylate
Anatomical site	Oral	Oral
Chemical safety	Non-hazardous	Non-hazardous
Sterility	Sterile	Not Sterile
Biocompatibility	Cytotoxic via ISO agarose overlay method	Cytotoxic via ISO agarose overlay method
Material consistency	hard	hard

Chemistry of Setting	 R = C_8H_{17}	 R varies (mix of butyl/octyl cyanoacrylate)
Working Time	1 second	<1 second
Setting Time	16.1 seconds	5.3 seconds
Bonding Strength	3.453 MPa (non-abraded substrate)/ 4.091 MPa (abraded substrate)	Unknown
Thermal Conductivity	0.1 W/mK	0.1 W/mK
Electrical Conductivity	1 x 10^{-13} S/cm	1 x 10^{-13} S/cm
Heat Generated during Setting	0.67°C / 0.01318 J 1.533 J/g	0.75°C / 0.02076 J 2.185 J/g
viscosity	V = 7.12 centistokes	unknown

PREDICATE DEVICE COMPARISON DISCUSSION

Oral Bond and the predicate device Periacryl both contain 2-octyl cyanoacrylate. PeriAcryl is a combination butyl and octyl cyanoacrylate. Butyl cyanoacrylate is known to be more cytotoxic that 2-octyl cyanoacrylate. Oral Bond and PeriAcryl utilize a process of adding agents to stabilize the polymerization of the cyanoacrylate and agents to increase viscosity and impart color. Oral Bond and all listed predicate devices will produce similar physical properties with similar tissue responses. The classification and indications for use are identical for both Oral Bond and PeriAcryl.

There are minor differences between the two products. Oral Bond is sterile and PeriAcryl is not sterile. The working time and set times were designed to be slower for Oral Bond than PeriAcryl in order to allow more time for dispensing and handling the material but also the slower working time and set time is beneficial because this reduces the heat generated during setting which can be significant for patient comfort if the periodontal dressing is being applied to teeth that are not anesthetized.

2-octyl cyanoacrylate has been proven to be suitable as a topical adhesive for many years.

The differences between the two devices are not critical to the intended therapeutic use of the device and the differences do not affect equivalence

CONCLUSION

Steiner Biotechnology, has demonstrated that, for the purposes of FDA's regulation of medical devices, the subject device, Oral Bond, is substantially equivalent to the predicate device in intended use, material composition, physical properties and principles of operation.