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 23, 2015

Dharma Research Inc.
Mr. Ricardo Carles
President
5220 NW 72nd Avenue #15
Miami, FL 33166

Re: K150696
Trade/Device Name: Jade 37% Phosphoric Acid Etchant Gel
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: February 3, 2015
Received: March 25, 2015

Dear Mr. Carles:

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,

for 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

Section 5 – Form FDA-3881 Indications for Use

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)*
K150696

Device Name
Jade 37% Phosphoric Acid Etchant Gel

Indications for Use *(Describe)*
A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.

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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

510(k) Summary

Date Prepared: 03 February 2015 **K 150696**

Device Common Name	Agent, tooth bonding, resin
Trade Name	*Jade 37% Phosphoric Acid Etchant Gel*
Classification Name	Resin tooth bonding agent
510(k) Submitter	Dharma Research, Inc. 5220 NW 72nd Avenue, Unit 15 Miami, Florida 33166
Contact	Ricardo Carles, President Telephone (305) 482-9669 Facsimile (305) 482-9670 E-mail: rcarles@dharmaresearch.com
Classification Regulation	21 CFR §872.3200
Device Class	II
Classification Panel	Dental
Product Code	KLE
Predicate Device	K112597, Seity 37% Phosphoric Acid Etchant Gel
Device Description	Thixotropic dental etchant gel with 37% phosphoric acid
Indications for Use	A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.
Technological characteristics	Thixotropic gel with 37% phosphoric acid, which is the same as the predicate device.
Bench testing	Both *Jade 37% Phosphoric Acid Etchant Gel* and the predicate device were tested for the following characteristics: • Percent phosphoric acid • pH • Viscosity • Consistency, Color and Odor Each test demonstrates the equivalence of *Jade* to the predicate device.

The information in this submission demonstrates that *Jade 37% Phosphoric Acid Etchant Gel* device is as safe, as effective, and performs as well the predicate device.

Substantial Equivalence

Product Name	*Jade* 37% Phosphoric Acid Etchant Gel	Seity 37% Phosphoric Acid Etching Gel
Sponsor	Dharma Research, Inc.	Mycone Dental
510(k)	K150696	K112597
Indication for Use	A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.	A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.
Phosphoric Acid	37%	37%
Consistency	Thick gel	Thick gel
Color	Blue or Green	Blue or Green
Odor	No characteristic	No characteristic
Viscosity	60,000 cps	40,000 cps
pH	1.52	1.20
Shelf-Life	Proposed 2-years, based on existing shelf-life studies (refer to Section 15)	Appears to be 2-years based on expiry date printed on label example in MISC files.
How Supplied	Pre-filled syringes with applicators, 1.2 ml, 12 g (10 ml), and 50 ml	Pre-filled syringe, 12 g
Applicator	Standard 23 ga bent Optional 25 ga bent	Not available

510(k) "Substantial Equivalence" Decision Making Process

Dec. No.	Question	Answer	Comment
1.	Is the predicate device legally marketed?	Yes	K112597
2.	Do the devices have the same intended use?	Yes	A thixotropic 37% phosphoric acid dental etchant gel for etching enamel, dentin, and glass ionomer cements to produce the necessary micro-retentive surface for successful bonding of restorations.
3.	Do the devices have the same technological characteristics?	Yes	The formula for *Jade* and the predicate are substantially equivalent, using thickeners and emulsifiers to provide a thick gel vehicle through which to deliver the phosphoric acid. The coloring agents are also substantially equivalent.

Conclusion

These key similarities and the results of the bench testing comparison demonstrate that *Jade* is substantially equivalent to the predicate product and raises no new issues of safety or efficacy. The formula for *Jade* and the predicate are very similar. Dharma Research was the contract manufacturer of the predicate product at the time that K112597 was cleared and for many years thereafter. Even though the chemical compositions are not identical, bench testing has demonstrated that *Jade* has comparable material properties and performance.