K122522

510(k) Summary

MAR 1 9 2013

1. **Name/Address of Submitter:** **Itena Clinical**

2. **Contact Person:**

Louis-Paul Marin
Co-President, BCF Certification inc.
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3. **Date Summary Prepared:** July 24, 2012

4. **Devices Names:** DentoEtch, Quickbond and Bond Activator
5. **Device Classification:** II

6. **Common name: Etching Gel and Resin tooth bonding agents**

7. **Classification Product Code: EBF (21 CFR 872.3690) and KLE (21 CFR 872.3200)**

8. **Predicate Devices:**

DentoEtch	**Kerr Gel Etchant K000954**		
Quickbond	**Premier Self-Etching Bond Enhancer K061998**	**Clearfil SE Bond K023842**	**Prime and Bond NT K982394**
Bond Activator	**Prime & Bond Activator K964525**	**Bond-1 Self-Cure Activator K013543**	

9. **Devices Description:**

DentoEtch: DentoEtch is an etching gel phosphoric acid 37%.

Quickbond: Simple to use, two-bottle, two step self-cure, self-etching bonding system, with a first bottle containing the primer and a second one containing the bonding agent. This subject device may also be used with a self-curing activator

resulted in cell reactions that have been interpreted as Moderate-severe and none, respectively, validating the test.

12. **Conclusion Drawn:** Based on their indications for use, technological characteristics and comparison to predicate devices, the subject devices have been shown to be safe and effective for their intended use.

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

March 19, 2013

Itena Clinical
C/O Mr. Louis-Paul Marin
Co-President
BCF Certification Incorporated
500 Boul Cartier West
Laval, Canada H7V 5B7

Re: K122522
Trade/Device Name: Quickbond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: January 15, 2013
Received: February 11, 2013

Dear Mr. Marin:

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,

Kwame O. Ulmer for

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

K122522

Indication for Use

Device Name: **DentoEtch**

Indication for Use:

It is intended used for etching tooth enamel and dentine when preparing surfaces for application of composites.

Device Name: **Quickbond**

Indication for Use:

It is intended for:

- Bonding composite to enamel and/or dentin;
- Bonding veneers, crowns & bridges, onlays and inlays
- Bonding composite core built-up material
- Bonding of composite to metal,
- Intraoral repairs (i.e. composite, fractured crowns & bridges, inlays & onlays and veneers);
- Treatment of hypersensitive teeth or exposed root surfaces; and
- Cavity sealing under amalgam restorations

Device Name: **Bond Activator**

It is intended for use to enable the practitioner to use self-cure techniques for the indications where dual-cured adhesive may be desired.

Concurrence of CDRH Office of Device Evaluation

Prescription Use _X_ OR Over-the-counter Use ____ (per 21CFR 801.109)

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

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