K123278

DEC 07 2012

Heraeus

510(k) Summary according to 21 CFR 807.92(c)

510(k) summary of safety and effectiveness information for iBond Self Etch (new formulation)

Submitter Information:	
Name	Heraeus Kulzer, LLC
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Phone Number	(574) 299- 5421
Fax Number	(574) 291- 0080
Establishment Registration Number	1925223
Name of Contact Person	Jamie Mearna
Date Prepared	December 3, 2012
Name of Device:	iBond Self Etch
Trade or Proprietary Name	iBond Self Etch
Common or Usual Name	Resin Tooth Bonding Agent
Classification Name Device Classification	Dental KLE Class II
Classification Panel:	76 Dental
Regulation:	21 CFR 872.3200
Product code (s):	KLE
Legally marketed devices(s) to which equivalence is claimed:	HK Bond K063062
Reason for 510(k) Submission:	This submission reports a modification to HK Bond K063062 regarding the addition of a stabilizer, change in rheological additive and storage requirements.
Device Description:	iBond Self Etch(new formulation is an acetone/water-based formulation of light activated methylacrylate resins.
Intended use of the device:	See indications for use below.
Indications for use:	iBond Self Etch (new formulation) it intended for use by dental professionals, for the bonding of direct light-cured composite restorations (including Polyglas® and copomers), bonding of indirect restorations in combination with a light curing luting cement; porcelain, polyglas®, and composite restorations (inlays, onlays, veneers crowns) and sealing hypersensitive areas of teeth.

Summary of the Technological Characteristics of the New Device Compared to the predicate Device HK Bond K063062:

The formula of the proven all-in-one adhesive has been refined. The modifications include the addition of a stabilizer the exchange of a rheological additive. The enhanced iBOND Self Etch_new formulation is now conveniently useable and storable at room temperature (up to 25°C). The adhesive no longer requires shaking. The product fulfills the internal specification. The basic fundamental scientific technology remains the same as well as the indications for use.

Similarities as Compared to Predicate:

	CLEARED iBOND Self Etch (BHT)- K063062	**NEW iBOND Self Etch (ISEA-EC)**
Content of BHT	750 ppm	Same
Indications for Use	iBOND Self Etch is used for bonding of direct light-cured composite restorations (including Polyglas® and copomers), bonding of indirect restorations in combination with a light-curing luting cement; porcelain, Polyglas®, and composite restorations (inlays, onlays, veneers, crowns) and sealing hypersensitive areas of teeth.	Same
Visual Appearance	Yellowish liquid, homogeneous, without sediment	Same
pH	<2,00	Same
Refractive index	1,421-1,426	Same
Application	Application in 1 layer	Same
Dwell time	20s	Same
Curing time	20s	Same
Compatibility	Compatible with direct light cured composite, light cured luting cement, porcelain,	Same

	Polyglas® and composite restorations	

Note: For formulation similarities as compared to predicate, please see section 11 of this submission.

Differences as Compared to Predicate:

	CLEARED iBOND Self Etch (BHT)- K063062	**NEW iBOND Self Etch (ISEA-EC)**
Shear Bond Strength	>15 MPa	≥20 MPa
Storage condition	Refrigeration required	No refrigeration required
Handling	Shaking necessary	No shaking necessary

Note: For formulation differences as compared to predicate, please see section 11 of this submission.

Results Summary:

The biological compatibility of iBOND Self Etch was verified in accordance with the international standard EN ISO 10993.
The medical devices iBOND Self Etch and new formulation were extracted with hydrophilic and lipophilic extraction medium according to EN ISO 10993-12. Leachable compounds detected in n-hexane, isopropanole and saline extracts are considered covered by the toxicological tests performed with iBOND Self Etch.
Considering the low exposure of the patient and animal welfare requirements, no in vivo toxicity studies were performed with the uncured or cured material.
The biocompatibility of iBOND Self Etch _new formulation in the aforementioned indication is documented and the benefit/risk-relation has to be judged as positive.
An allergenic potential in predisposed persons cannot be excluded completely due to the presence of monomers such as acrylates and methacrylates.

Conclusions Drawn From Non-Clinical and Clinical Data:

The refined formula of the proven all-in-one adhesive is substantially equivalent to cleared iBOND Self Etch.
A biocompatibility evaluation has been performed by a toxicologist for iBOND Self Etch _new formulation. It was confirmed that the product meets the requirements of ISO 10993 and it is concluded that the safety of iBOND Self Etch _new formulation is equivalent to that of the predicate device.
The risk analysis acc. ISO 14791 was carried out for iBOND Self Etch _new formulation. It is concluded that safety of iBOND Self Etch _new formulation for the intended use is substantially equivalent to the predicate device. iBOND Self Etch_new formulation and the predicate

formula have the same indication for use, warnings and contraindications. When used in accordance with the instruction for use, by qualified personnel, iBOND Self Etch _new formulation is safe and effective, as indicated for the 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 20993-002

December 7, 2012

Ms. Jamie Mearna
Associate Quality Assurance & Regulatory Manager
Heraeus Kulzer, Limited Liability Company
300 Heraeus Way
SOUTH BEND IN 46614

Re: K123278
Trade/Device Name: iBond Self Etch
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: September 25, 2012
Received: November 19, 2012

Dear Ms. Mearna:

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

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

Indications for Use

510(k) Number (if known): K123278

Device Name: **iBond Self Etch**

Indications for Use:

iBond Self Etch is an acetone/water-based formulation of light-activated methylacrylate resins.

iBond Self Etch is used for bonding of direct light-cured composite restorations (including Polyglas® and copomers), bonding of indirect restorations in combination with a light-curing luting cement; porcelain, Polyglas®, and composite restorations (inlays, onlays, veneers, crowns) and sealing hypersensitive areas of teeth.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

2012.12.07
Susan Runner DDS, MA 15:06:19
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: _____