



Food and Drug Administration
10903 New Hampshire Avenue
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July 7, 2015

Heraeus Kulzer, LLC, Mitsui Chemicals Group
Ms. Jamie L. Cleveland
Associate Quality Assurance & Regulatory Affairs Manager
3001 Heraeus Way
South Bend, IN 46614

Re: K150933
Trade/Device Name: iBond Universal and iBond Ceramic Primer
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE, EBF
Dated: March 10, 2015
Received: April 8, 2015

Dear Ms. Cleveland:

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 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>. 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,

 Tina
Kiang -S

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

Enclosure

Indications for Use

510(k) Number (if known): K150933

Device Name: **iBond Universal & iBond Ceramic Primer**

Indications for Use:

The iBond Universal System consists of iBond Universal bonding agent and iBond Universal Ceramic Primer. The iBond Universal indications are: Bonding of direct restoration for all cavity classes (Black) using light curing, dual curing or self-curing methacrylate based composites/composers, Bonding of light curing dual curing or self-curing core build up materials, sealing of hypersensitive tooth areas, sealing of cavities prior to amalgam restorations, bonding of fissure sealants, sealing of cavities and core preparations prior to temporary cementation of indirect restorations(according to the immediate dentin sealing technique), cementation of indirect restorations with light curing dual-curing or self-curing adhesive resin cements, intraoral repair of composite and compomer restorations, porcelain fused to metal, all ceramic as well as metal restorations.

The iBond Ceramic Primer indications are; surface conditioning of silicate/glass ceramic, specifically for the fixation of indirect restorations with luting composites, for intraoral repair of ceramic veneerings, as well as full ceramic restorations.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)