K083652

Heraeus

Summary of safety and effectiveness of the adhesive iBOND® Total Etch (=IBTE)

JAN 21 2009

1 Description and intended use of the medical device

iBond® Total Etch is an improved light-cured single-component adhesive for use in adhesive restorative dentistry and was developed within the scope of the project IBTE on the base of an ethanol solution of light-activated, adhesive resins The material is characterized by the following properties in detail

- The material has been developed for the adhesive bonding of plastic filling materials (e g composites, compomer, Polyglas®) to dental hard substance and laboratory-fabricated restorations (e g ceramics)
- With iBOND® Total Etch, priming, bonding and desensitizing can be done in one step
- Before using iBOND® Total Etch, the dental hard substance is conditioned with iBOND® Etch 35 Gel (etch&rinse)

In its unpolymerized state, the adhesive material is workable similar to current products
Cross linking reaction is initiated with light curing (QTH, LED) devices customary in dental technology
Cross-linking of the methacrylate monomers occurs very fast, ensuring reliable curing of the adhesive layer

Thus, a highly cross-linked material results, fully complying with the mechanical requirements for a dental adhesive material

2 Indication list

- Adhesive fixing of direct composite, Polyglas® and compomer restorations
- Adhesive fixing of indirect laboratory-fabricated ceramic, Polyglas® and composite restorations
- Treatment of hypersensitive tooth regions

3 Biocompatibility Evaluation

In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1

The biological compatibility of the prototype IBTE was verified in accordance with the international standard The cured adhesive did not show a significant toxicological reaction

The biocompatibility of iBond® Total Etch in the aforementioned indication was documented in a biocompatibility evaluation report and the benefit/risk-relation has been judged as positive

4 Physical properties

iBond® Total Etch was developed with focus to a simple and safe application
The physical properties of iBond® Total Etch were determined in comparison with current products
The results have shown equal or better properties of iBond® Total Etch to the current Heraeus and various competitive products

5 Clinical Evaluation

In accordance with the medical Device directive 93/42/EWG and national European medical device legislation, any medical device is requested to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety This includes a clinical evaluation in accordance with MEDDEV 2 7 1 , which is intended to critically evaluate the clinical benefits of the medical device in comparison to its potential risks Therefore, any clinical evaluation is part of the compulsory risk management process according to EN ISO 14971, and critical findings must further be considered in the current risk management process of the medical device manufacturer responsible for the evaluated device

On this background, the clinical evaluation was performed in order to comply with the current european medical device legislation, in particular with MEDDEV 2 7 1 This critical evaluation followed the procedures outlined in the corresponding clinical evaluation plan

iBond® Total Etch is a light-cured single-component adhesive, which is generally classified as a class IIa medical device under the Medical Device Directive 93/42/EEC The material has been developed for the adhesive bonding of plastic filling materials (e g composites compomer, Polyglas®) to dental hard substance and laboratory-fabricated restorations (e g ceramics), intended for long-term application

Considering the evaluated scientific data and technical results for iBond® Total Etch it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable, when weighed against their benefits in dentistry Therefore, a positive risk versus benefit ratio can be stated by the expert for iBond® Total Etch, provided that the product applied in accordance with its intended use as outlined in the manufacturer s instruction for use

The clinical evaluation report was prepared in accordance with MEDDEV 2 7 1 and followed the provisions of the corresponding clinical evaluation plan

6 Summarized Evaluation

The risk potential of the developed adhesive iBond® Total Etch was proved with the laboratory prototype and a prototype from production All properties of the prototype were verified successfully The risk potential of the developed material iBond® Total Etch was proven with the prototype from laboratory and production

The biological compatibility of the adhesive material was investigated to evaluate the toxicological risk A certified laboratory has confirmed that the product iBond® Total Etch meets the requirements of the DIN EN ISO 10993 standard The results were discussed in a Biocompatibility Evaluation Report and the benefit/risk-relation has been judged as positive

The physical properties of iBond® Total Etch were determined in comparison with current products The results have shown equal or better properties of iBond® Total Etch to the current Heraeus and various competitive products

Based on the results of the clinical evaluation report it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighted against their benefits in dentistry

The risk analysis (according to DIN EN ISO 14971) was carried out for the composition of the prototype iBond® Total Etch and showed that the application of iBond® Total Etch could be considered to be safe

iBond® Total Etch meets all requirements relevant for dental adhesive material in accordance with the Medical Device directive 93/42/EEC and national European medical device legislation Based on the actual facts iBond® Total Etch could be evaluated to be effective and safe with its intended use as outlined in the manufacturer s instruction for use

Wehrheim, 24 09 2008

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JAN 21 2009

Re K083652
Trade/Device Name IBond Total Etch
Regulation Number 21 CFR 872 3200
Regulation Name Resin Tooth Bonding Agent
Regulatory Class II
Product Code KLE and LBH
Dated December 8, 2008
Received December 9 2008

Dear Ms Zimmerman

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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), 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K083652

Device Name **iBOND TOTAL ETCH**

Indications for Use

- Bonding of direct composite, Polyglas® and compomer restorations
- Bonding of indirect laboratory-fabricated ceramic, Polyglas and composite restorations (inlays, onlays, veneers and crowns)
- Treatment of hypersensitive tooth regions

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)

Susan Runner

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

510(k) Number K083652