K101064

# >>510(k) Summary

bredent

510(k) Summary as required by section 807.92(c)

Date: 03/15/10

Submission Applicant:
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SEP 1 4 2010

Establishment Registration Number:
1000303432

Application correspondent/Contact person:
Andrea Pecsi
Think!
Schwarzwaldstrasse 5
78532 Tuttlingen
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**Trade name:**
**K101064 - bredent novo.lign A / novo.lign P**

**Common name:**
**Preformed plastic tooth / artificial PMMA teeth**

**Classfication name:**
**Preformed plastic denture tooth, Dental (21 CFR 872.3590 - ELM)**

**Predicate Device:**
**K962456 – SR Antaris anterior teeth/SR Postaris posterior teeth**

**Description of the Device:**
Bredent novo.lign A / novo.lign P artificial are multi-layer veneers for anterior and posterior teeth. Theses teeth devices are chemically based on polymethacrylate-polymers and their chemical properties. These preformed plastic dentures are used when fabricating any kind of dental restauration (see application range beneath).

**Indications for Use:**
The bredent novo.lign A / novo.lign P are preformed plastic denture teeth as a prefabricated device, composed of materials such as polymethylmethacrylat and methylmethacrylat that are intended for use as veneers. The bredent novo.lign A / novo.lign P are used for temporary or partial or full dentures.

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***Permanent veneering:***
· telescopic and conical crowns
· CoCr clasp restorations
· crowns and bridges
· implant-supported restorations
· coverdenture techniques

***Veneer-up:***
· selection of esthetic shade, shape and tooth position

***Temporary restorations:***
· laboratory-made temporaries based on impression and wax-up
· veneer on temporary abutments after placement of the implant

The devices are offered in non-sterile condition.

**Technological characteristics compared to the Predicate Device**

The bredent product is similiar to the predicate device in terms of technical characteristics, design, Indications for Use, target population, where it is used, performance, biocompatibility characteristics as well as sizes and configurations. **Therefore the bredent product can be deemed substantially equivalent and safe and effective for its indicated use.**

**Non-clinical performance data**

Bredent certifies compliance with the requirements of the following device relevant standards: ISO 7405 "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry", ADA / ANSI ADA Specification No.15 " Synthetic Polymer Teeth", and ISO 22112 "Dentistry - Artificial teeth for dental prostheses". Moreover product evaluations in application of the directive 93/42/EEC have been performed on the bredent novo.lign A / novo.lign P devices.

**Summary**

**The presented data that was conducted on the bredent products shows in its results and in comparison to the predicate device that the products perform as well as or better than the predicate device, safe and effective for their intended use and do not raise any questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market in Europe for many years with no device failures. The used materials are well researched and do not raise any kind of question regarding safety and effectiveness of the finished product.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bredent GmbH & Company KG
C/O Ms. Andrea Pecsi
Regulatory Affairs Specialist
Think!
Schwarzwald Strasse 5
D-78532 Tuttlingen, BaWü
Germany

SEP 1 4 2010

Re: K101064
Trade/Device Name: Bredent novo.lign A / novo.lign P
Regulation Number: 21 CFR 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: August 4, 2010
Received: August 18, 2010

Dear Ms. Pecsi:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

510(k) Number: K101064

Device Name:
bredent novo.lign A / novo.lign P

## Indications for use:

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

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

Concurrence of DCRH, Office of Device Evaluation (ODE)



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

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