510(k) Summary

Submitter Name: Vertex Dental B.V.
Submitter Address: Johan van Oldenbarneveltlaan 62,
3705 HJ Zeist
The Netherlands

Phone Number: 31 30 69 767 49
Fax Number: 31 30 69 551 88

Contact Person: William Greenrose
Contact Address: 220 River Rd.
Claremont, NH 03743

Phone Number: 603-369-3550
Fax Number: 603-369-3562

Date Prepared: August 9, 2010

Device Trade Name: Vertex Self Curing, Vertex Castavaria, Vertex Castapress

Common Name: Denture base material

Classification Name, Number & Product Code: resin, denture, relining, repairing, rebasing
872.3760
EBI

Predicate Devices: Probase Cold (K913655), Major Repair (K082153)

Device Description and Statement of Intended Use

Device Description: Vertex cold-curing denture base materials are self curing acrylic denture base materials composed of polymethyl methacrylate powder and a liquid consisting of methyl methacrylate and other ingredients. The polymer is shaded to simulate the color of gum tissue using pigments that are approved for alimentary or similar use and are Cadmium free. The devices covered in this submission are the Vertex Self Curing, Vertex Castavaria, and the Vertex Castapress denture base materials.

Vertex™ Self Curing is a self-curing acrylic denture base material intended for the repair and relining of full and partial dentures, made by heat-curing acrylics. This acrylic can be polymerized in 10 minutes using a pressure vessel.

Vertex™ Castavaria is a multifunctional self polymerizing denture base material intended as a pouring and as a repair acrylic. The advantages of this acrylic are: minimized shrinkage, color stability, stable polymerization cycle and the acrylic is pourable for a long period of time. In addition Vertex™ Castavaria can be worked and modeled over a relatively long period of time.

Vertex™ Castapress is a self polymerizing pouring/casting type denture base material also suitable for repair, relining, rebasing and extensions of partial dentures. The colour stability of the material is excellent because of the use of an unique accelerator system

The Vertex Cold-Curing denture base materials are substantially equivalent to predicate denture base devices presently on the USA market and safety and effectiveness are well documented in dental literature.

Intended Use:

Vertex cold-curing denture base materials are indicated for:

1. Manufacture of full and partial dentures
2. Repair of full and partial dentures
3. Rebasing of full and partial dentures
4. Relining of full and partial dentures

Summary of Technological Characteristics

All of the components found in Vertex™ cold-curing denture base materials have been used in legally marketed devices and were found safe for dental use.

o

Summary of Technical Characteristics

Feature	**Vertex Cold-Curing Denture base material**	**Probase Cold**	**Major Repair**
510(k) Number	Not yet assigned	K913655	K082153
Manufacturer	Vertex Dental B.V.	Ivoclar	Major Prodotti Dentari S.p.a
Classification # & Product Code	872.3760 EBI	872.3760 EBI	872.3760 EBI
Indications for Use	Vertex cold-curing denture base materials are indicated for: 1. Manufacture of full and partial dentures 2. Repair of full and partial dentures 3. Rebasing of full and partial dentures 4. Relining of full and partial dentures	The cold-curing ProBase Cold is suitable for both the pouring and the packing technique. **Indication** – Partial dentures – Combination dentures – Relining – Repairs – Complete dentures	Major.Repair is a cold-curing polymer for dental prosthesis. Poly-methylmethacrylate based. For reparing and rebasing dentures. Powder and liquid. It is used to: - repair and rebase prosthesis - temporary prosthesis
Physical Properties	**flexural strength**: Vertex Self Curing: 68 MPa Vertex Castavaria: 79 MPa Vertex Castapress: 75 MPa **flexural modulus**: Vertex Self Curing: 2028 MPa Vertex Castavaria: 2316 MPa Vertex Castapress: 2293 MPa **water absorption**: Vertex Self Curing: 20.3 µg/mm^3 Vertex Castavaria: 23.2 µg/mm^3 Vertex Castapress: 22.1 µg/mm^3 **Water solubility**: Vertex Self Curing:1.8 µg / mm^3 Vertex Castavaria: 1.8 µg / mm^3 Vertex Castapress:1.19 **± 0.18** µg / mm^3 **Residual monomer**: Vertex Self Curing: 3.76 ± 0.15% Vertex Castavaria: 3.91 ± 0.05% Vertex Castapress: 3.22 ± 0.06%	**flexural strength**: 63.44 ± 4.24 MPa **flexural modulus**: 1832.00 ± 88.87 MPa **Residual monomer**: <4.5%	**flexural strength**: 66.4 MPa **flexural modulus**: 2217 MPa **water absorption**: 21.2 µg/mm^C **Water solubility**: 1.4 µg / mm^3 **Residual monomer**: 4.0%
Standards of Conformity	ISO 1567 ISO 20795 ISO 179-1 ISO 7405 ASTM F 895-84	ISO 1567	ISO 1567

Substantial Equivalence	The Vertex cold-curing denture base materials are substantially equivalent to the Probase Cold (K913655) and Major Repair (K082153), with respect to mode of action and intended use. It is substantially equivalent to the Probase Cold (K913655) and Major Repair (K082153) denture base materials, with respect to material of composition. The submitted devices pose the same types of questions about safety or effectiveness as the existing device.
Conclusion	The information discussed above demonstrates that the Vertex cold-curing denture base materials are substantially equivalent to the predicate devices.
Declarations	o This summary includes only information that is also covered in the body of the 510(k). o This summary does not contain any puffery or unsubstantiated labeling claims. o This summary does not contain any raw data, i.e., contains only summary data. o This summary does not contain any trade secret or confidential commercial information. o This summary does not contain any patient identification information.

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

Vertex Dental B.V.
C/O Mr. William F. Greenrose
Qserve America
220 River Road
Claremont, New Hampshire 03743

MAR 2 5 2011

Re: K102640
Trade/Device Name: Vertex Self Curing
Vertex Castavaria
Vertex Castapress
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: March 22, 2011
Received: March 23, 2011

Dear Mr. Greenrose:

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,

Anthony D. Watson

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

Indications for Use

510(k) Number (if known): K102640

Device Name: Vertex Self Curing
Vertex Castavaria
Vertex Castapress

Indications For Use:

Vertex cold-curing denture base materials are indicated for:

1. Manufacture of full and partial dentures
2. Repair of full and partial dentures
3. Rebasing of full and partial dentures
4. Relining of full and partial dentures

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page 1 of 1

510(k) Number: K102640