JUVORA
DENTAL INNOVATIONS

JAN 23 2014

5. 510(k) Summary

K132725

Company:	Juvora
Date:	October 24, 2013
Contact Person:	Selina Shaw Technology Centre Hillhouse International Thornton-Clevelys Lancashire FY5 4QD UK Tel: +44 (0)1253 898000 Fax: +44 (0)1253 898001 Date of Preparation: 27th August 2013
Proprietary Name:	Juvora Dental Disc
Common Name:	Dental resin
Classification:	Denture Relining, Repairing, Rebasing Resin (21 CFR 872.3760, Product Code EBI; Regulatory Class II)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed

- Vertex Thermosens Rigid (K123220)
- Paladon Ultra (K111832)

Device Description

JUVORA™ Dental Discs are cylindrical, puck-shaped discs made from the implant-grade polymer, PEEK-OPTIMA® LT1, that are used in the CAD/CAM manufacture of removable dental prostheses. The discs are provided either with or without a step.

Indications for Use

The Juvora Dental Disc is a thermoplastic dental disc for the manufacture of full and partial removable dentures and implant overdentures.

Summary of Technological Characteristics

The Juvora Dental Disc has similar indications for use as the predicates: Vertex Thermosens Rigid (K123220) and Paladon Ultra (K111832). The Juvora Dental Disc and predicate devices are made from different thermoplastics but meet the same recognized standards in regards to strength (ISO 20795-1 Denture Base Polymers) and biocompatibility (ISO 7405 – Dentistry Evaluation of biocompatibility of medical devices used in dentistry).

Summary of Non-Clinical Performance Data

Testing is performed in compliance with applicable clauses of ISO 20795-1 (Equivalent to **ANSI/ADA** Specification No. ***12:2002/ISO* 1567:1999** - Denture Base Polymers).

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Substantial Equivalence Conclusion
Results from the testing to ISO 20795-1 and substantial equivalence justification provided within this 510(k) demonstrate that the Juvora Dental Disc is as safe and effective and performs as well as the predicate devices for the proposed indications.

Summary of Biocompatibility Testing
The standard: Dentistry – Evaluation of biocompatibility of medical devices used in dentistry ISO 7405:2008 and the JUVORA™ Dental Disc has been assessed in terms of biocompatibility according to ISO 10993-1:2009, Evaluation and testing within a risk management process. Using ISO 10993-1:2009 the JUVORA™ Dental Disc was categorised: permanent contact with the mucosal membrane and has been tested accordingly and is biocompatible. The results of the tests completed demonstrate no evidence of cytotoxicity, systemic toxicity, irritation or any macroscopic reaction response. As there is no evidence that any harmful leachable ingredient and/or residues are contained and/or released, no further toxicity was required on the JUVORA™ Dental Disc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 23, 2014

JUVORA Dental Innovations
Ms. Selina Shaw
Regulatory Affairs Officer
Technology Centre
Hillhouse International
Thornton-Clevelys
Lancashire, FY5 4QD
UK

Re: K132725
Trade/Device Name: JUVORA™ Dental Disc
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: October 24, 2013
Received: October 25, 2013

Dear Ms. Shaw:

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,

Kwame O. Ulmer for
-S FDA

Erin I. Keith, M.S.
Acting 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 Statement

510(k) Number (if known): K132725

Device Name: Juvora Dental Disc

INDICATIONS FOR USE:
The Juvora Dental Disc is a thermoplastic dental disc for the manufacture of full and partial removable dentures and implant overdentures.

Prescription Use ___X___ **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS MA Mary S. Runner -S 2014.01.22 13:17:32 -05'00'