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

Juvora, Ltd.
Tim Leyva
Regulatory Leader -United States
Technology Centre, Hillhouse International
Thornton-cleveleys, FY5 4QD GB

February 13, 2017

Re: K160918
Trade/Device Name: Juvora Dental Disc, Ceramill Peek By Juvora
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, EBF, EBG
Dated: January 19, 2017
Received: January 23, 2017

Dear Tim Leyva:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160918

Device Name
JUVORA™ Dental Disc

Indications for Use *(Describe)*

The JUVORA™ Dental Disc is a thermoplastic dental disc. They are intended to be used for the manufacture of:

i) full and partial removable dentures and implant overdentures.

ii) copings, substructures (cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgework.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K160918

I. SUBMITTER

Name:	Juvora, Ltd.
Address:	Technology Centre, Hillhouse International Thornton-Clevelys Lancashire FY5 4QD UK
Phone:	484.354.4185
Email:	tim.leyva@invibio.com
Contact Person:	Tim Leyva
Date Prepared:	January 10, 2017

II. DEVICE

Name of Device:	JUVORA™ Dental Disc
Common or Usual Name:	Dental Resin
Product Code & Classification:	EBI - Denture Relining, Repairing, Rebasing Resin *21 CFR 872.3760* EBG – Crown And Bridge, Temporary, Resin *21 CFR 872.3770* EBF – Material, Tooth Shade, Resin *21 CFR 872.3690*
Regulatory Class:	II

III. PREDICATE DEVICE

510(k) Number	Trade or Proprietary or Model Name	Manufacturer	TYPE
K132725	JUVORA™ DENTAL DISC	Juvora, Ltd.	Predicate Device
K133608	TRINIA	Bicon, LLC	Reference Device

IV. DEVICE DESCRIPTION

JUVORA™ Dental Discs are cylindrical, puck-shaped discs made from the polymer, PEEK-OPTIMA™ LT1, that are used in the CAD/CAM manufacture of removable dental prostheses. The disc is provided non-sterile, without any accessories, and are single use.

The JUVORA™ Dental Discs are provided in a variety of sizes:

Ø 95 x 16 mm
Ø 95 x 20 mm

Ø 98 x 16 mm
Ø 98 x 18 mm
Ø 98 x 20 mm
Ø 98 x 22 mm
Ø 98 x 25 mm
Ø 98 x 30 mm

Ø 101 x 13 mm
Ø 101 x 20 mm

V. INDICATIONS FOR USE

The JUVORA™ Dental Disc is a thermoplastic dental disc. They are intended to be used for the manufacture of:

i) full and partial removable dentures and implant overdentures.

ii) copings, substructures (cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgework.

VI. TECHNOLOGICAL CHARACTERISTICS

	New Device	**Predicate Device**	**Reference Device**
Manufacturer	Juvora, Ltd.	Juvora, Ltd.	Bicon, LLC
Trade Name	JUVORA™ DENTAL DISC	JUVORA™ DENTAL DISC	TRINIA
510(k) Number	K160918	K132725	K133608
Indications for Use	The Juvora Dental Disc is a thermoplastic dental disc. They are intended to be used for the manufacture of: i) full and partial removable dentures and implant overdentures. ii) copings, substructures (cemented or uncemented), frameworks for permanent and transitional anterior or posterior crowns and bridgework.	The Juvora Dental Disc is a thermoplastic dental disc for the manufacture of full and partial removable dentures and implant overdentures.	Fiber Disks and Blocks (TRINIA) are intended to be used for making copings, substructures, removable dentures, or frameworks for permanent and transitional anterior or posterior crowns, bridgework, and substructures that can be for either cemented or uncemented restorations (e.g. telescopic restorations).

JUVORA
DENTAL INNOVATIONS

	New Device	Predicate Device	Reference Device
Material	PEEK-OPTIMA™ LT1	PEEK-OPTIMA™ LT1	Glass fiber Modified epoxy resin
Shape	Disc	Disc	Disc
Flexural Strength	192 MPa (ISO 10477) 165 MPa (ISO 20795) 194 MPa (ISO 6872)	192 MPa (ISO 10477) 165 MPa (ISO 20795) 194 MPa (ISO 6872)	393 MPa (ISO 14125)
Flexural Modulus	3995 MPa (ISO 20795)	3995 MPa (ISO 20795)	18.8 GPa (ISO 14125)
Water Absorption	5 (µg/mm3) (ISO 20795) 5.0 (µg/mm3) (ISO 10477) 0.5% (wt) (ISO 62)	5 (µg/mm3) (ISO 20795) 5.0 (µg/mm3) (ISO 10477) 0.5% (wt) (ISO 62)	0.03%
Shear Bond Test	Dental composite veneer system (GC Gradia, GC) 27.3 MPa (ISO TR 11405) Dental cement system (RelyXUltimate, 3M ESPE) 21.2 MPa (ISO TR 11405)	Dental composite veneer system (GC Gradia, GC) 27.3 MPa (ISO TR 11405) Dental cement system (RelyXUltimate, 3M ESPE) 21.2 MPa (ISO TR 11405)	-
Technology	Polymer disc for the manufacture of dental frameworks in accordance with indications of use	Polymer disc for the manufacture of dental frameworks in accordance with indications of use	Polymer disc for the manufacture of dental frameworks in accordance with indications of use

	New Device	Predicate Device	Reference Device
Principles of Operation	The dental disc is to be converted into dental frameworks using CAD/CAM technology (computer-aided design and computer-aided manufacturing)	The dental disc is to be converted into dental frameworks using CAD/CAM technology (computer-aided design and computer-aided manufacturing)	The dental disc is to be converted into dental frameworks using CAD/CAM technology (computer-aided design and computer-aided manufacturing)

JUVORA™ is expanding the indications for use for the JUVORA™ Dental Disc (*510(k) K132725*) to include copings, substructures, frameworks for permanent and transitional anterior or posterior crowns and bridgework. The predicate device is Juvora's own device.

VII. NON-CLINICAL PERFORMANCE DATA

The JUVORA™ Dental Disc has been tested in the following test modes:

- Mechanical testing per ISO 10477, ISO 20795 and ISO 7405.
- Biocompatibility for material composition of PEEK-OPTIMA™ per ISO 10993.

The results of this non-clinical testing show that the strength of the JUVORA™ Dental Disc is sufficient for its intended use and is substantially equivalent to the legally marketed predicate device.

VIII. CONCLUSIONS

The overall technology characteristics and mechanical performance data lead to the conclusion that the JUVORA™ Dental Disc is substantially equivalent to the predicate device.