



Food and Drug Administration
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November 25, 2015

Opal Orthodontics By Ultradent Products
Marie Hess
Sr. Regulatory Affairs Associate
505 West 10200 South
South Jordan, Utah 84095

Re: K152779

Trade/Device Name: Avex Cx2
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: October 13, 2015
Received: October 15, 2015

Dear Ms. Marie Hess:

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,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. In the background, there is a faint, large watermark of the letters "FDA".

Erin I. Keith, M.S.
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

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K152779

Device Name

Avex CX2

Indications for Use (Describe)

Avex® CX2 ceramic brackets are intended for use in orthodontic treatment.

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.

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"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."

K152779

Section 5: Special 510(k) Summary

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

Opal Orthodontics by Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person: Ms. Marie Hess
Title: Sr. Regulatory Affairs Associate
Telephone: 800-552-5512 x4610, 801-553-4610
FAX: 801-553-4609

Date Summary Prepared: 22 September, 2015

II. Name of the Device

Trade Name: Avex® CX2
Common Name: Ceramic Bracket
Device Classification: Class II
Classification Product Code: NJM
Regulation No. 21 CFR 872.5470

III. Predicate Device:

Avex CX2, ceramic brackets are a modification of Avex CX₂ and Avex CXi₂, cleared under 510(k) K113334, also manufactured by Opal Orthodontics by Ultradent Products. Avex CX₂ and Avex CXi₂ are made from polycrystalline alumina (ceramic). They come in two prescriptions; McLaughlin and Opal R, with two slot sizes; .018 and .022. These brackets have the same measurement designators found in all orthodontic brackets such as angle of torque; angulation; in/out; slot height, depth, length; and dimensions of the auxiliary slot. Avex CX₂ is a bracket consisting of only the ceramic material while the Avex CXi₂ has a stainless steel metal slot liner to help reduce friction between the material of the bracket in the slot and the arch wire. They are translucent and have the same basic forms as other ceramic brackets like tie wings and hooks so as to facilitate their intended use.

Indications for use of predicate device:

Avex CX₂ and Avex CXi₂ ceramic brackets are intended for use in orthodontic treatment.

**IV. Device Description
of subject device:**

Avex[®] CX2 ceramic brackets are intended to be bonded to teeth upon which an orthodontic wire is placed in a slot to re-position the teeth to desired positions. Avex CX2 ceramic brackets are manufactured from polycrystalline alumina (ceramic) material and have a base which has been designed to provide adhesion to the tooth, yet allow for removal when necessary. The raw material has been documented to be biocompatible for its intended contact and duration of contact. There are several other products in the market that have the same indications as these products and the proposed modification does not affect composition, intended use, or indications for use. Opal Orthodontics has followed design control processes outlined in 21 CFR 820.30 and internal procedures to complete our design control procedure and documentation for the Avex CX2.

Avex CX2 ceramic brackets are esthetically preferred as ceramic colored arch wires are available and the vision of “metal mouth” is no longer the case for the bracket wearer. These ceramic brackets and certain arch wires are intended to match natural tooth coloring in order to reduce visibility.

Avex CX2 ceramic brackets are indicated for use in patients of all ages when prescribed by a dentist or orthodontist.

**V. Indications for use of
subject device:**

Avex CX2 ceramic brackets are intended for use in orthodontic treatment.

VI. Comparison of technological characteristics

Avex CX₂ and Avex CXi₂, (K113334), and Avex CX2 have similar technological characteristics:

Table 5-1: Substantial equivalence comparison

Characteristic	Predicate: Avex CX₂ and Avex[®] CXi₂, (K113334)	Avex[®] CX2
Indications for Use	Avex CX ₂ and Avex CXi ₂ , (K113334) are intended for use in orthodontic treatment.	Avex CX2 ceramic brackets are intended for use in orthodontic treatment.
Intended user	Dental or Orthodontic professional	Dental or Orthodontic professional
Material Characteristics	Polycrystalline alumina (ceramic)	Polycrystalline alumina (ceramic)
Physical Properties	Tie wings for ligature wires and identification marks for placement	Tie wings for ligature wires and identification marks for placement
	Molded ceramic body with rounded corners, edges, and hooks, and physically prepared base.	Molded ceramic body with rounded corners, edges, and hooks, and physically prepared base.
	Available in .018 and .022 slot sizes and various prescriptions	Available in .018 and .022 slot sizes and various prescriptions
Compliance to applicable standard(s)	Complies to ISO 27020:2010	Complies to ISO 27020:2010
Biocompatibility	Device demonstrated through literature studies to be non-toxic per ISO 10993-1	Device demonstrated through literature studies to be non-toxic per ISO 10993-1

The Avex[®] CX2 is composed of polycrystalline alumina, which has been widely used by manufacturers in the dental industry for more than 2 decades. The efficacy or

suitability to the intended purpose of Avex CX2 has been demonstrated by a combination of in-house testing and side-by-side comparisons to predicate devices currently on the market. Results of our testing document that Avex CX2 is substantially equivalent in performance to predicate devices currently on the market.

Avex CX2 has been tested for bond strength, de-bond evaluations, and adhesive shear strength evaluation and met all other design inputs. The Avex CX₂ and Avex CXi₂ has been tested for bond strength, de-bond evaluations, and adhesive shear strength evaluation and met all other design inputs. The comparative results of the testing demonstrated that the modified Avex CX2 is substantially equivalent to the predicate, Avex CX₂ and Avex CXi₂.

No clinical performance testing was performed on Avex CX2, ceramic brackets.

In conclusion, Avex CX2, ceramic brackets, have been designed and manufactured with the intended use and claims for the product in mind. Published literature, bench test data, and risk/benefit reviews have been collected and evaluated to determine substantial equivalence in safety and effectiveness of similar devices and the Avex CX2 bracket for the same indications. Therefore, the modified version Avex CX2, is substantially equivalent to Avex CX₂ cleared under K113334.