K1B334

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Section 5

Traditional 510(k) Summary

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 .92.

Applicant's Name and Address

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

Contact Person:	Diane Rogers
Title:	Manager of Regulatory and International Affairs
Telephone:	(800) 552-5512 x4491, (801) 553-4491
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Date Summary Prepared:	November 10, 2011

Name of the Device

Device:	Bracket, Ceramic, Orthodontic
Device Name:	AVEX® CX_2 and AVEX® CXi_2
Regulation Number:	CFR 872.5470
Device Class:	Class II
Product Code:	NJM

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate devices are: K973776 Reflections Ceramic Brackets by CDB Corporation.
AVEX® CX_2 and AVEX® CXi_2 ceramic brackets are substantially equivalent to our predicate devices in terms of intended use, indications for use, composition, device design and performance. There are several other products in the market that have the same indications as these products. We chose K973776 Reflections Ceramic Brackets by CDB Corporation as they tested most similar to AVEX® CX_2 and AVEX® CXi_2 ceramic brackets.

Indications for Use: AVEX® CX_2 and AVEX® CXi_2 ceramic brackets are intended for use in orthodontic treatment.

Product Description: AVEX® CX_2 and AVEX® CXi_2 ceramic brackets are intended to be bonded to teeth, upon which an orthodontic wire is placed to move the teeth to desired positions. AVEX® CX_2 and AVEX® CXi_2 Ceramic brackets are manufactured from polycrystalline alumina (ceramic) material and have a base which has been designed to provide maximum adhesion to the tooth, yet allow for easy and complete removal when necessary.

The brackets incorporate a water soluble color placement dot as an indicator for correct selection of brackets for each tooth.

AVEX® CX_2 and AVEX® CXi_2 are the exact same brackets except AVEX® CXi_2 has a stainless steel 17-4 insert inside the archwire slot which will facilitate archwire movement without force and preventing "notching" of the slot.

The AVEX® CX_2 brackets are aesthetically preferred as ceramic colored archwires are now available and the vision of "metal-mouth" is no longer the case for the bracket wearer. These ceramic brackets and certain arch wires are close to natural tooth coloring and blend in well enough that they are not as visible as metal brackets or ceramic brackets with metal inserts and metal archwires. This aesthetic look is popular with many patients and especially older patients.

AVEX® CX_2 and AVEX® CXi_2 ceramic brackets are indicated for use in patients of all ages when prescribed by a dentist or Orthodontist.

Similarities in the Indications for Use

Device	510(k) number	Indications for Use
AVEX® CX_2 and AVEX® CXi_2		AVEX® CX_2 and AVEX CXi_2 Ceramic brackets are intended for use in orthodontic treatment
K973776 Reflections Ceramic Brackets With and without metal inserts	(K973776)	Reflections Ceramic Brackets are cemented to the front surface of the tooth where they direct the mechanical forces that urge teeth into the correct alignment.

Attributes	K973776 Reflections Ceramic Brackets	Opal Orthodontics AVEX® CX_2	Opal Orthodontics AVEX® CXi_2
Polycrystalline Alumina Material	X	X	X
Metal Slot Liner	X		X
Tie Wings for Ligature Ties	X	X	X

Traditional 510(k) for AVEX® CX_2 and CXi_2 Ceramic Brackets

Color dots for Identification	X	X	X
Available in .018 & .022 slot sizes	X	X	X
Available in Roth® Prescription	X	X	X
Available in MBT® Prescription	X	X	X
Available in McLaughlin Prescription		X	X

Substantial Equivalence

The test data indicates that AVEX® CX_2 and AVEX® CXi_2 Ceramic Brackets are substantially equivalent in safety and effectiveness for their use in orthodontic treatment and perform as well or better than predicate devices in terms of intended use, composition, device design, and performance. This 510(k) also includes data from bench testing to evaluate the performance of AVEX® CX_2 and AVEX® CXi_2 compared to the predicate devices.

Technological Characteristics

AVEX® CX_2 and AVEX® CXi_2 Ceramic Brackets are substantially equivalent in design features to the predicate devices. The AVEX® CX_2 is a ceramic bracket with an arch wire slot that does not have a metal liner. The AVEX® CXi_2 is the same exact ceramic bracket with the addition of a stainless steel 17-4 slot liner. Predicate brackets are manufactured to meet specifications for different prescriptions. We follow the same prescriptions including the newly released McLaughlin prescription.

Our products consist of ceramic brackets with the following advantages:

- .018 and .022 slot sizes
- Roth® prescription
- McLaughlin prescription
- MBT® prescription
- Ceramic orthodontic bracket with and without metal slot liner

Device Material

AVEX® CX_2 and AVEX® CXi_2 and our predicate devices all have a bracket body made of polycrystalline alumina ceramic. The AVEX® CXi_2 contains a metal slot liner made from 17-4 Stainless steel. All AVEX® CX_2 and AVEX® CXi_2 Ceramic brackets have a water soluble color indicator dot on them as our predicates have.

Device Design

AVEX® CX_2 and AVEX® CXi_2 ceramic brackets have tie-wing undercut spaces for orthodontic ligatures. They have a molded ceramic bracket body with rounded corners and edges, which replaces the angular profile of machined ceramic brackets, and rounded hooks on the distal-gingival tie-wings.

Brief Description of Testing Performed

The following bench tests were conducted during the R & D phase on AVEX® CX_2 and AVEX® CXi_2 compared to K973776 Reflections Ceramic Brackets by CDB Corporation.

Final test results are in Section 18 "Bench Testing".

- The **bond strength** measures the force required to de-bond a bracket when a force is applied. The test results showed that the bond strengths of AVEX® CX_2 and AVEX® CXi_2 and our predicates are comparable and exceed the minimum bond strength to hold the bracket to the tooth.
- **Doctor de-bond testing** was evaluated and documented that when de-bonding the brackets the bond strength was not excessive to cause enamel damage to the tooth.
- **The adhesive shear strength evaluation for AVEX CXi_2 ceramic bracket slot liner test** measures the forces applied to the vertical slot in AVEX® CX_2 and AVEX® CXi_2 brackets which cause the metal insert to de-bond from the slot. The test results show that de-bond adhesives we selected for AVEX® CXi_2 metal slot liners are more consistent and stronger to that of our predicate's bracket adhesive.

Clinical Performance Testing

No clinical performance testing was conducted on AVEX® CX_2 and AVEX® CXi_2 Ceramic brackets.

Clinical Summary

A complete Clinical Summary of AVEX® CX_2 and AVEX® CXi_2 is included in Section 20. We conducted a literature study to show safety and effectiveness of AVEX® CX_2 and AVEX® CXi_2. The product line includes many skus for different sizes and shapes of ceramic brackets and ceramic brackets with metal slot liners to fit a variety of teeth shapes and selected prescriptions. AVEX® CX and AVEX® CXi can be used on any age patient when treatment is prescribed by a dentist or Orthodontist.

AVEX® CX_2 and AVEX® CXi_2 ceramic brackets are made of the exact same materials and technological characteristics as K973776 Reflections Ceramic Brackets by CDB Corporation.

Our research shows that these materials have been widely used by numerous manufacturers in the dental industry for more than 2 decades.

The efficacy or suitability to the intended purpose of AVEX® CX_2 and AVEX® CXi_2 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 indicates that AVEX® CX_2 and AVEX® CXi_2 perform as well or better than the predicate devices currently on the market.

Summary
Risk/Benefit Review

Considering the safe history of our predicates, K973776 Reflections Ceramic Brackets by CDB Corporation, AVEX® CX_2 and AVEX® CXi_2 ceramic brackets are substantially equivalent and considered to be safe medical devices. Our research indicates that our predicate has been used by many dentists and large group practices in the United States and purchased by a large number of international distributors. To date, there have been no reported complaints of local or systemic adverse effects associated with the use of the predicate product.

Biocompatibility testing according to ISO 10993-1:2009 was not conducted on our ceramic brackets and metal slot liners as the biocompatibility of polycrystalline alumina (ceramic) and stainless steel 17-4 has been shown by many other predicate device manufacturers over the past decades. Our literature search of biocompatibility testing shows that these components of the brackets are safe and effective.

Conclusion

In conclusion, AVEX® CX and AVEX® CXi ceramic brackets have been designed and manufactured with the intended use and claims for the product in mind. Scientific literature, test data etc. has been collected and evaluated to determine safety and efficacy of similar products used for the same indication. Following the clinical review as documented above, Opal Orthodontics by Ultradent Products, Inc. deems that when these devices are used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of the patient and the association with its use constitutes acceptable risks when weighed against the benefits to the patient. Therefore, these products are compatible with a high level of protection of health and safety and may be released to the market.

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

FEB - 3 2012

Ms. Diane Rogers
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Opal Orthodontics
10200 South 505 West
South Jordan, Utah 84095

Re: K113334
Trade/Device Names: AVEX® CX_2 and AVEX® CXi_2
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: November 10, 2011
Received: November 14, 2011

Dear Ms. Rogers:

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

Statement of Indications for Use

510(k) Number (if known): K113334

Device Name: AVEX® CX_2 and AVEX® CXi_2

Indications for Use:

AVEX® CX_2 and AVEX® CXi_2 Ceramic Brackets are intended for use in Orthodontic treatment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Susan Runner

n Sign-Off)
n of Anesthesiology, General Hospital
ion Control, Dental Devices

(k) Number: K113334