K122753

AMERICAN ORTHODONTICS

DEC 14 2012

# 510(k) Summary



**Preparation Date: August 28, 2012**

**Company Information:**

American Orthodontics
1714 Cambridge Avenue
Sheboygan, WI 53081
Phone: 920-457-5051
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**Contact Information:**

Trang Adams / Regulatory Affairs Specialist
1536 N. 18th Street
Sheboygan, WI 53081
Phone: 920-457-5051 Ext. 4251
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**Device Information:**

Trade Name: Empower Clear
Common Name: Ceramic Brackets
Classification Name: Bracket, Ceramic, Orthodontic
Classification Code: NJM
Regulation Number: 872.5470

**Equivalent Legally Marketed Devices Information:**

| 510(k) # | Product Name | Device Manufacturer |
|---|---|---|
| K080749 | Radiance | American Orthodontics |
| K060837 | In-Ovation C | Densply |

**Description of the Device:**

The Empower Clear line of products is single-use devices intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth. The Ceramic Bracket combines the aesthetics of a ceramic bracket with the versatility and ease of self ligation.

These brackets are comprised of several geometries that vary from bracket to bracket, corresponding to the intended tooth. These geometries contribute to the fit of the bracket to the tooth and also impart the axial control of the energy from the archwire.

**Indications for Use:**

Empower Clear brackets are intended for orthodontic movement of teeth as diagnosed by an orthodontist. It is used temporarily and is removed upon completion of orthodontic treatment. Empower Clear brackets are intended to be single use only.

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**Technological Characteristics Information:**
The material, Alumina Oxide [$Al_2O_3$], is used in the manufacturing of the Radiance brackets and In-Ovation C brackets – which is the same material used for Empower Clear.

The In-Ovation C clip material is the same as the Empower Clear clip material. The Radiance bracket does not have a clip.

The function and performance of the Empower Clear brackets are substantially equivalent to the predicate devices, as outlined in the following table.

| | Device Name / Manufacturer | | | |
|---|---|---|---|---|
| **Product Parameter** | **Radiance / American Orthodontics** | **In-Ovation / Dentsply** | **Empower / American Orthodontics** | **Substantial Equivalence Analysis** |
| **510(k) Number** | K080749 | K060837 | Pending | N/A |
| **Material** | $Al_2O_3$ | $Al_2O_3$ | $Al_2O_3$ | Equivalent |
| **Intended Use** | Orthodontic treatment is used to correct dental deficiencies and to improve the appearance of the patient. The brackets, arch wire and elastic o-rings form a force system that is designed to gradually move teeth into a normal alignment. | The Innovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid teeth. | Ceramic Brackets are intended for orthodontic movement of teeth as diagnosed by an orthodontist. It is used temporarily and is removed upon completion of orthodontic treatment. Ceramic Brackets are intended to be single use only. | Equivalent |
| **Single Use** | YES | YES | YES | Equivalent |
| **Non-Sterile Packaging** | YES | YES | YES | Equivalent |

**Biocompatibility Testing:**
Biocompatibility testing conducted on Empower Clear brackets indicates that the bracket material is safe for use. The bracket material, Aluminum Oxide [Al2O3], was found to be free of harmful extractables. No oral mucosa irritation or skin sensitization was detected with the material.

**Summary:**
The function and performance of Empower Clear bracket is similar to the predicates. There are no changes in the intended use and fundamental scientific technology. All of the materials used in the device have been used in legally marketed American Orthodontics devices. Minor differences in

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technological characteristics do not raise new types of safety and effectiveness questions.

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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

December 14, 2012

Mr. Trang Adams
Regulatory Affairs Specialist
American Orthodontics
1536 North 18th Street
SHEBOYGAN WI 53081

Re: K122753
Trade/Device Name: Empower Clear
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: October 23, 2012
Received: October 26, 2012

Dear Mr. Adams:

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,

Susan Runner DDS, MA 2012.12.14 10:46:01 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use Statement

**510(k) Number (if known):** K 122753
Unknown

**Device Name:**
Empower Clear

**Indications for Use:**
Empower Clear brackets are intended for orthodontic movement of teeth as diagnosed by an orthodontist. It is used temporarily and is removed upon completion of orthodontic treatment. Empower Clear brackets are intended to be single use only.

**Prescription Use And/Or Over-The-Counter Use:**

- Prescription use by orthodontist only
- Not available Over-The-Counter [OTC]

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

**510(k) Number:** K122753

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