



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2008

Mr. Jerome H. Schomberg
Vice President-Engineering
American Orthodontics Corporation
1714 Cambridge Avenue
Sheboygan, Wisconsin 53081

Re: K080749
Trade/Device Name: Radiance
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket \\\nRegulatory Class: II
Product Code: NJM
Dated: July 8, 2008
Received: July 14, 2008

Dear Mr. Schomberg:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRII's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K080749

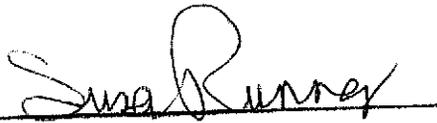
RADIANCE: 510(k) NUMBER K080749

ADDENDUM TO THE SUBMITTAL OF MARCH 7, 2008

STATEMENT OF INDICATIONS FOR USE

Radiance is an orthodontic bracket. Orthodontic brackets are prescribed for patients with teeth that are not normally positioned in the mouth. An orthodontic bracket is a device consisting of a base, an arch wire slot and four tie wings. The bracket bases are attached to a patient's teeth with adhesive. A metal arch wire is placed in the arch wire slot of a set of brackets (typically ten brackets on each of the upper and lower arches) and the wire is held in place in each bracket slot with an elastic o-ring placed under the tie wings and over the arch wire.

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. Radiance brackets can enhance the patient's appearance during treatment because the bracket is highly transparent. These brackets are less visible than metal brackets and are preferred by many patients – especially adults.



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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