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

May 15, 2015

Progressive Technology, Inc.
Ms. Shannon Rogers
President
4130 Citrus Ave #17
Rocklin, California 95677

Re: K142729
Trade/Device Name: Chi Lites Orthodontic Sapphire Bracket
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: II
Product Code: NJM
Dated: April 6, 2015
Received: April 6, 2015

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 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" (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 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 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

2. Indications for Use

510 (k) Number: K142729

Device Name: Chi Lites Orthodontic Sapphire Bracket

Indications for use:

The Progressive Technology Inc. Chi Lites Orthodontic Sapphire Bracket is a line of single-use devices intended for orthodontic movement of teeth.

The bracket is used temporarily and is removed upon completion of orthodontic treatment.

Prescription Use ___x___ AND/OR Over-the Counter Use _____

5. 510(K) Summary

Preparation Date: September 22, 2014

Company Information:

Shannon Rogers
Progressive Technology, Inc.
4130 Citrus Avenue
Rocklin, CA 95677

Contact Information:

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Device Information:

Trade Name: Chi Lites Orthodontic Sapphire Bracket
Common Name: Ceramic Brackets
Classification Name: Orthodontic Plastic Bracket
Classification Code: NJM bracket, ceramic, orthodontic
Regulation Number: 872.5470
Device Classification: Class II

Equivalent Legally Marketed Devices Information:

Predicate	510(k)	Product Name	Device Manufacturer
Primary	K080749	Radiance	American Orthodontics
Reference	K060837	In-Ovation C	Dentsply

Description of the Device:

Progressive Technology Inc. is submitting this Premarket Notification for its Class II product, an orthodontic sapphire bracket. The device is intended for use in conjunction with comprehensive orthodontics to control the movement of individual teeth.

The 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:

The Progressive Technology Inc. Chi Lites Orthodontic Sapphire Bracket is a line of single-use devices intended for orthodontic movement of teeth.

The bracket is used temporarily and is removed upon completion of orthodontic treatment.

	Device Name/Manufacturer			
Product Parameter	Chi Lites Orthodontic Sapphire Bracket/ Progressive Technology	Radiance / American Orthodontics	In-Ovation C / Dentsply	Substantial Equivalence Analysis
510(k) number	Pending	Primary K080749	Reference K060837	N/A
Intended Use	The Progressive Technology Inc. Chi Lites Orthodontic Sapphire Bracket is a line of single-use devices intended for orthodontic movement of teeth as diagnosed by an orthodontist.	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 In-Ovation C is intended for orthodontic movement of natural teeth, excluding the mandibular bicuspid teeth.	Equivalent
Target Population	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Patients in need of teeth alignment correction	Equivalent
Anatomical Site	Teeth	Teeth	Teeth	Equivalent
Location of Use	Use only by professional orthodontists	Use only by professional orthodontists	Use only by professional orthodontists	Equivalent
Technical Characteristics	Chi Lites Orthodontic Sapphire brackets are .019 square inches, 5% larger than other brackets.	.018 square inches of area in size	.018 square inches of area in size	Difference: Chi Lites Orthodontic Sapphire brackets are 5% larger, thus increasing the facture toughness. There are no other differences.
Single Use	YES	YES	YES	Equivalent
Non-Sterile Packaging	YES	YES	YES	Equivalent

Performance Testing

Two tests were preformed on the Chi Lites Orthodontic Sapphire bracket.

A. Fracture testing. Used to determine the maximum amount of force that can be applied to the product during treatment. The Bracket archwire is placed on a calculated wedge designed to split the bracket at full depth of the archwire. Force is then applied to the base of the bracket until the amount of force fractures/splits the bracket. The results are then recorded.

   This process was performed on 20 brackets, 10 of the Chi Lites Orthodontic Sapphire bracket and 10 of the predicate bracket. The results show that the Chi Lites Orthodontic Sapphire bracket was stronger than the predicate bracket by almost 2X. Since the predicate bracket is a cleared bracket, we feel the Chi Lites Orthodontic Sapphire Bracket meets the minimum requirements for strength.

B. Bond/Shear Strength. Used to determine the strength of the bonding surface when adhered to the tooth. A UV curing adhesive is applied to the base of the bracket and mounted to the testing surface i.e. porcelain, ceramic or extracted teeth. The Adhesive is cured and the bracket is then tied to a pull test gauge and force is applied until the bracket separates from the bonding surface. The results are then recorded.

   This process was performed on 40 brackets 20 of the Chi Lites Orthodontic Sapphire bracket and 20 of the predicate bracket, both of similar size and orientation. The results show both bracket brands averaged within .005% of each other. The Chi Lites Orthodontic Sapphire bracket range of bond strength was within 40% of the average while the predicate was within 45% of its average bond strength. Chi Lites Orthodontic Sapphire bracket proved to be 5% more consistent than the predicate bracket.

Summary:

The function and performance of Chi Lites Orthodontic Sapphire 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 cleared orthodontics devices. Since the subject and predicate are similar in design, function and performance, they are substantially equivalent to the predicate device.