K093821

AUG 27 2010

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

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Wendy Garman - Contact Person

Date Summary Prepared: August 2010

Device Name:

- Trade Name – FS Aligner
- Common Name – Aligner, Sequential
- Classification Name – Orthodontic Plastic Bracket, per 21 CFR § 872.5470

Devices for Which Substantial Equivalence is Claimed:

- Align Technology, *Invisalign*
- Red, White & Blue, *Allessee Orthodontic Appliances*

Device Description:

FS Aligner is an aligner system which offers a solution to those patients who want a simple, aesthetic system of removable aligners to correct minor anterior mal-alignments in patients with permanent dentition (second molars) without the use of conventional wire and bracket orthodontic technology. The system consists of a series of clear, lightweight, flexible, plastic aligners. Each aligner applies incremental progressive force to reposition teeth to a more ideal alignment as prescribed by the treating dental practitioner.

The practitioner will make a dental impression of the patient's teeth and select the teeth that are to be repositioned (corrected). The impressions, or models of the teeth made from the impression, are sent to AOA with a prescription form. The mold will be scanned and the resulting electronic mold with be altered within the computer program to both determine the

degree of correction and to offer the practitioner the opportunity to review, alter, and approve of the digital corrections. Once approved, the teeth on the physical mold(s) will be sequentially repositioned by hand followed by the fabrication of an aligner for that stage of progressive correction. After 5-7 progressive corrections the resulting aligners are returned to the practitioner for delivery to the patient. Once that sequence of treatment is completed the practitioner will submit a new impression or bite registration to AOA laboratories for the manufacture of the next group or sequence of progressive corrections and aligners. Depending on the complexity of the mal-alignment it is possible that a patient may require 1-8 such iterations of 5-7 aligners.

The *FS Aligner* system will be mailed (shipped) to the practitioner, who in turn, will provide them to their patient with instructions for use.

Intended Use of the Device:

The *FS Aligner System* is intended for minor anterior tooth movement in patients with permanent dentition (second molars). The *FS Aligner System* positions teeth by way of continuous gentle force.

Summary of Technological Characteristics:

FS Aligner is substantially equivalent to other legally marketed devices in the United States. *FS Aligner* functions in a manner similar to and is intended for the same use as *Invisalign* that is currently marketed by Align Technology and *Red, White & Blue* that is currently marketed by Allessee Orthodontic Appliances.

Features	*FS Aligner*	*Invisalign*	*Red, White & Blue*
Intended Use	A series of clear plastic aligners intended for treatment of tooth malocclusion by way of a continuous gentle force. Each aligner is produced using manually created individual molds each incorporating a progressive correction.	A series of clear, plastic aligners (from 1 – to over 100) intended for treatment of tooth malocclusion by way of a continuous gentle force. Each aligner produced through computerized generation of individual molds each incorporating a progressive correction.	A series of 3 clear, plastic retainers intended to be used to correct minor to intermediate tooth mal-alignments by moving teeth progressively to a final, treated state.
Aligner Material	Thin thermo formed plastic material.	Thin thermo formed plastic material.	Thin thermo formed plastic material.

Mode of Use	Each appliance is worn by the patient as determined by the treating dental practitioner, generally 2-4 weeks prior to being replaced by the next aligner in sequence.	Each appliance is worn by the patient as determined by the treating dental practitioner, generally 2weeks prior to being replaced by the next aligner in sequence.	Each appliance is worn by the patient for 2-4 weeks, or until the patient feels the appliance is passive, in the appropriate sequence of Red, White & Blue retainers.
Description of Appliance Application	Removable	Removable	Removable
Manufacturing Method	Each set up and aligner is manually formed. The technician will cut the desired teeth from the mold and will progressively reposition the teeth required to meet the prescript goal of alignment. The set up portion of the process will be guided by a computerized version of the set up providing information similar to a "blueprint" for the technician. After each repositioning the technician will create a corresponding aligner for a total of 5-7 aligners. These will be returned to the practitioner and delivered to the patient. Following the completion of wear by the patient a new bite registration or impression is returned to the laboratory (AOA) for the next sequence of aligners to be fabricated. This system of "reboot" and acquiring benchmarks to further correct the mal-alignment is continued as needed.	The aligners are manufactured through the use of three-dimensional laser scanning technology – scanning the patient's mold into computer software. From the scanned image, and following a practitioner's prescription, the software generates the image of the final, treated state and then interpolates a series of images that represent intermediate states of alignment. The resulting computer "set ups" relay this information to rapid prototyping machines that produce the physical molds and the aligners are produced from each mold to produce the sequence of aligners.	The retainers are manually formed. The technician will cut the desired teeth from the mold and will progressively reposition the teeth. After each repositioning the technician will create a corresponding appliance for a total of 3 active appliances.

Non-Clinical Test Data:

Biocompatibility studies (cytotoxicity, irritation and sensitization) have been completed which demonstrates that the material used to produce the *FS Aligner* is safe for its intended use.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility and similar technological characteristics to the predicate devices, the performance of the *FS Aligner* is deemed to be substantially equivalent to *Invisalign* and *Red, White & Blue.*

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

Allesee Orthodontic Appliances
C/O Ms. Wendy Garman
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

AUG 27 2010

Re: K093821
Trade/Device Name: FS Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: July 30, 2010
Received: August 2, 2010

Dear Ms. Garman:

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

K093821

Indications for Use

510(k) Number (if known):

Device Name: *FS Aligner*

Indications For Use:

The FS Aligner System is intended for minor anterior tooth movement in patients with permanent dentition (second molars). The FS Aligner System positions teeth by way of continuous gentle force.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

R&Betz DDS for Dr Susan Runner

ision Sign-Off

vision of Anesthesiology, General Hospital

fection Control, Dental Devices

10(k) Number: K093821