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AUG 14 2012

P.O. Box 99 St. Ann, Missouri 63074 Office 314.426.4020 Fax 314.429.7575 WWW.DYNAFLEX.COM

5. 510(k) Summary

Submitter:

DynaFlex
10403 International Plaza Dr.
St. Ann, MO 63074

Contact:

Matthew Malabey
Quality & Regulatory
DynaFlex
314-426-4020– Phone
314-429-7575– Fax

Date Summary Prepared: May 7th, 2012

Device Name:

- Trade Name – EZ-Align®
- Classification name – Sequential Aligner
- Regulation Description – Orthodontic plastic bracket
- Definition – The device moves by gentle force for treatment of minor tooth malocclusion
- Regulation Medical Specialty – Dental
- Review Panel – Dental
- Product Code – NXC
- Regulation Number 21 CFR§ 872.5470
- Device Class – 2

Devices for Which Substantial Equivalence is Claimed (Predicated Devices):

- Allesee Orthodontic Appliance Inc. – *Red, White & Blue* (K040874)
- Specialty Appliance Works, Inc.– Clear Image™ Aligner (K071970)
- Clear Correct, Inc.– Clear Correct (K082556)

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Device Description:

DynaFlex ® EZ-Align® Appliance is a series of up to four, clear, lightweight, plastic retainers intended to be used to correct minor (1.5mm or less to inter canine/cusped crowding) anterior tooth misalignment in patients in permanent dentition by moving teeth progressively to a final, treated state.

The device will be custom made for each patient and will be sold by prescription. The device is manufactured with medical grade thermo plastic that is standard throughout the industry.

Aligners are fabricated from .030 thermoformed polycarbonate plastic. The mechanism of force application to the teeth is via intentional distortion of the plastic as the aligners are seated in the mouth. Each subsequent aligner in the overall progressive series is made from a mold of the patient's teeth which reflect subtle changes in the position of the teeth from the previous aligner. The positional changes are introduced into each aligner in the laboratory by moving the teeth on the construction model and then forming the aligner on the same model. The overall treatment is prescribed by the dentist to the laboratory where they are fabricated.

Aligners may be adjusted by the dentist. Aligners are completely removable by the patient and treatment may be discontinued at any time. The appliance if provided as a non-sterile device and single use.

Statement of Intended Use:

DynaFlex ® EZ-Align® Appliance is a series of up to four, clear, lightweight, plastic retainers intended to be used to correct minor (1.5mm or less to inter canine/cusped crowding) anterior tooth misalignment in patients in permanent dentition by moving teeth progressively to a final, treated state. DynaFlex EZ-Align® is for prescription only.

Summary of Technological Characteristics:

Section 5.0: 510(k) Summary Submitter: DynaFlex® EZ-Align® Premarket Notification: Traditional 510(k): A dental health care professional (e.g. Orthodontist or Technological dentist), prescribes the EZ-Align® system based on an characteristics assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth, and completes a prescription form The molds and prescription are sent to Dynaflex. DynaFlex designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. DynaFlex produces the trays, which are fabricated from .030 thermoformed polycarbonate plastic. The mechanism of force application to the teeth is via intentional distortion of the plastic as the aligners are seated in the mouth. Each subsequent aligner in the overall progressive series is made from a mold of the patient's teeth which reflect subtle changes in the position of the teeth from the previous aligner. The positional changes are introduced into each aligner in the laboratory by moving the teeth on the construction model and then forming the aligner on the same model. The overall treatment is prescribed by the dentist to

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the laboratory where they are fabricated. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicates referenced above.

Performance Characteristics:

Bench testing of the Aligners has not been performed due to the difficulty in evaluating this type of dental device in a laboratory setting. However, there is sufficient information available from the scientific literature & other legally FDA cleared device of similar characteristics to demonstrate that the preformed tooth positioner provides reasonable assurance of safety and effectiveness. Biocompatibility testing was performed according to ISO 10993 and that all testing passed.

Substantial Equivalence:

DynaFlex® EZ-Align® is substantially equivalent to other FDA approved legally marketed orthodontic devices in the United States. *EZ-Align® Aligners* is used in a manner similar to the *Clear Image™* system marketed by Specialty Appliance Works, Inc., and Align Technology *Red, White & Blue* marketed by Allesee Orthodontic Appliances., and *Clear Correct* marketed by Clear Correct, Inc. The proposed and predicate devices are of similar design; made from virtually identical materials, and are fabricated using similar manufacturing methods that are common to the dental device industry. Furthermore, DynaFlex® EZ-Align® Appliance have the same intended uses as the predicate devices in that they serve as an oral appliance constructed of polymer components that when fabricated into their final form and dimensions, are a dental appliance that are custom fit for the patient. The properties and characteristics of the predicate devices are compared to DynaFlex® EZ-Align® Devices in the Table 12-1.

Table 12-1
Substantial Equivalence Comparison

Manufacturer:	DynaFlex®	ALLESEE ORTHODONTIC APPLIANCES	Specialty Appliances Works, Inc.	ClearCorrect, Inc.
Trade Name:	*EZ-Align®*	*RED, WHITE & BLUE®*	*Clear Image™Aligners*	*ClearCorrect™*
Product Images:				
Product Code:	NXC	NXC	NXC	NXC
Attach Mechanism: (lower to upper tray)	None	None	None	None
Regulation Number:	872.5470	872.5470	872.5470	872.5470

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Regulation Name:	Orthodontic plastic bracket	Orthodontic plastic bracket	Orthodontic plastic bracket	Orthodontic plastic bracket
510(k):	TBD	K040874	K071970	K082556
Statement of Intended Use:	*DynaFlex ® EZ-Align® Appliance is a series of up to four, clear, lightweight, plastic retainers intended to be used to correct minor (1.5mm or less to inter canine/cusped crowding) anterior tooth misalignment in patients in permanent dentition by moving teeth progressively to a final, treated state. DynaFlex EZ-Align® is for prescription only.*	ALLESEE ORTHODONTIC APPLIANCES: Red, While & Blue Is a series of three, clear. lightweight, plastic retainers intended to be used to correct minor to intermediate anterior tooth mal-alignments in patients with permanent dentition (second molars) by moving teeth progressively to a flnal, treated state. The Dentist makes final decision and adjustment per treatment plan	Specialty Appliances' Clear ImageTM Aligners primarily are directed toward treating a patient's anterior teeth. Such treatment involves the relatively minor orthodontic tooth movements intended to impact a patient's appearance and self image. The Dentist makes final decision and adjustment per treatment plan	The CearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System, positions teeth by way of continuous gentle force. The Dentist makes final decision and adjustment per treatment plan
Mechanism of Action:	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive force from the Sequential Retainers is limited.	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive force from the Sequential Retainers is limited.	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive force from the Sequential Retainers is limited.	Basic mechanics follows the same principles of conventional orthodontics. The aligners apply a simple force on the tooth. Therefore, the Sequential aligners can produce tipping, rotation, extrusion and intrusion forces. However, the extrusive force from the Sequential Retainers is limited.
Materials:				
Stainless Steel:	None	None	None	None
Dental Plastic:	Thermoformed polycarbonate (Plastic)	Thermoformed polycarbonate (Plastic)	Thermoformed polycarbonate (Plastic)	Thermoformed polycarbonate (Plastic)
Dimensions:	Various (see Engineering Drawings)	Various (Not available)	Various (Not available)	Various (Not available)
Supplied Sterile:	No	No	No	No
Single Use:	Yes (i.e., multiple use by the same patient)	Yes (i.e., multiple use by the same patient)	Yes (i.e., multiple use by the same patient)	Yes (i.e., multiple use by the same patient)
Worn at Night:	Yes	Yes	Yes	Yes
Patient Population	Patient with Permanent Dentition	Patient with Permanent Dentition	Patient with Permanent Dentition	Patient with Permanent Dentition
Physical Properties	Plastic Sheets/Proprietary	Plastic Sheets/Proprietary	Plastic Sheets/Proprietary	Plastic Sheets/Proprietary

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

DYNA FLEX
Mr. Matthew Malabey
Quality & Regulatory Manager
10403 International Plaza Drive
St. Ann, Missouri 63074

AUG 14 2012

Re: K121396
Trade/Device Name: DynaFlex® EZ-Align®
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: May 07, 2012
Received: July 19, 2012

Dear Mr. Malabey:

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

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SECTION 4—INDICATION FOR USE

510(k) Number (if known):_____

Device Name:

DynaFlex ® EZ-Align®

Indications for Use:

DynaFlex ® EZ-Align® Appliance is a series of up to four, clear, lightweight, plastic retainers intended to be used to correct minor (1.5mm or less to inter canine/cusped crowding) anterior tooth misalignment in patients in permanent dentition by moving teeth progressively to a final, treated state. DynaFlex EZ-Align® is for prescription only.

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

Susan Runner

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

510(k) Number: K123946