K071970

5. 510(k) Summary

SEP 25 2007

510(k) Summary of Safety and Effectiveness

Submitter:

Specialty Appliances Works, Inc.
4905 Hammond Industrial Drive
Cumming, GA 30041

Contact:

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International Legal Consultant
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Date Summary Prepared July 2007
Resubmitted September 2007

Device Name:

- Trade Name – Clear Image™ Aligners
- 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:

- Align Technologies – *Align System*
- Allesee Orthodontic Appliances – *Red, White & Blue*

Device Description:

Specialty Appliances' Clear Image™ 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 aligners are

fabricated in clear, thin, thermoformed plastic in a sequential series to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner.

Aligners are fabricated from .035 or .040 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.

Specialty Appliances fabricates its aligners from the prescription of an orthodontist or dentist. The dentist selects the teeth to be repositioned and indicates the type of movements desired. The patient's plaster models are then supplied to the laboratory by the attending orthodontist. The model is prepared to allow repositioning the target teeth. Next, an aligner is formed over the master model with the slightly altered to positions. As an aligner with a positionally-biased tooth receiving compartment is seated in the mouth, the positional distance between each compartment and its corresponding living tooth causes a subtle change in the semi-elastic structure of the aligner. In order for a slightly out of register aligner compartment to engage its target tooth, the material surrounding the aligner compartment becomes elastically loaded as if the plastic structure of the aligner were a spring. The subtle pressure of the aligners stored energy acts similar to a spring does when it is loaded. It is the slow dissipation of the stored energy in the structure of the aligner that urges the root structures of the teeth to move through the supportive bone.

Intended use of the Device:

The Clear Image™ Aligners system is intended to correct minor discrepancies in the alignment of maloccluded anterior teeth on patients with permanent dentition (second molars) by moving the teeth with a progressive series of clear thin, thermoformed plastic aligners, fabricated in stages to gradually align the teeth over a period of several months. The aligners are completely removable by the patient and may be discontinued at any time.

Substantial Equivalence:

Clear Image™ Aligners is substantially equivalent to other FDA approved legally marketed orthodontic devices in the United States. *Clear Image™ Aligners* is used in a manner similar to the *Invisalign* system, *K981095,* marketed by Align Technology and *Red, White & Blue, K040879,* marketed by Allesee Orthodontic Appliances.

4905 Hammond Industrial Drive • Cumming, Georgia 30041 • 1-800-LAB-INFO • 678-513-4408 • Fax 678-513-7345

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Specialty Appliances Works, Incorporated
C/O James W. Kolka, Ph.D., J.D.
International Legal Consultant
2193 Spear Point Drive
Marietta, Georgia 30062

SEP 25 2007

Re: K071970
Trade/Device Name: Clear Image™ Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: July 10, 2007
Received: July 17, 2007

Dear Dr. Kolka:

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.

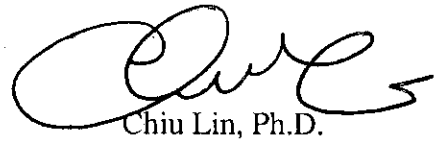
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Division of Anesthesiology, General Hospital,
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Radiological Health

Enclosure

SPECIALTY APPLIANCES

ORTHODONTIC LABORATORY SERVICES

Indications for Use

510(k) Number (if known): K071970

Device Name: Clear Image™ Aligners

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Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)

Division of Anesthesiology, General Hospital

Infection Control, Dental Devices

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