

K080246

**510(k) SUMMARY**

**APR 11 2008**

DENTSPLY International  
Susquehanna Commerce Center West  
221 West Philadelphia Street, Suite 60  
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: January 28, 2008

TRADE OR PROPRIETARY NAME: COMPOSITE ALIGNER BUTTON

CLASSIFICATION NAME: Sequential Aligner NXC 872.5470

PREDICATE DEVICES: Align System K981095  
Thermoform Sheet Materials and Accessories K072522

DEVICE DESCRIPTION: The COMPOSITE ALIGNER BUTTON is made of plastic and is bonded to an aligner for attaching elastics and other appliances.

INTENDED USE: The COMPOSITE ALIGNER BUTTON is an accessory that is attached to dental or orthodontic aligners to assist in minor tooth movement.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the COMPOSITE ALIGNER BUTTON have been used in legally marketed devices and/or were found safe for dental use. Appropriate biocompatibility testing has been completed.

We believe that the prior use of the components of the COMPOSITE ALIGNER BUTTON in legally marketed devices and the biocompatibility data provided support the safety and effectiveness of the COMPOSITE ALIGNER BUTTON for the indicated uses.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 11 2008

Ms. Helen Lewis  
Director of Corporate Compliance and Regulatory Affairs  
DENTSPLY International, Incorporated  
Susquehanna Commerce Center West  
221 West Philadelphia Street, Suite 60  
York, Pennsylvania 17405-0872

Re: K080246  
Trade/Device Name: Composite Aligner Button  
Regulation Number: 21 CFR 872.5470  
Regulation Name: Orthodontic Plastic Bracket  
Regulatory Class: II  
Product Code: NXC  
Dated: April 7, 2008  
Received: April 9, 2008

Dear Ms. Lewis:

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.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K080246

## INDICATIONS FOR USE STATEMENT

510(k) Number (if known): \_\_\_\_\_

Device Name: COMPOSITE ALIGNER BUTTON

### Indications for Use:

The COMPOSITE ALIGNER BUTTON is an accessory that is attached to dental or orthodontic aligners to assist in minor tooth movement.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Robert Betz D.D.S. for Dr. Susan Kummer*  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:  K080246

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