K072522

510(k) SUMMARY

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

CONTACT: Helen Lewis

NOV 1 6 2007

DATE PREPARED: SEP 0 6 2007

TRADE OR PROPRIETARY NAME:
THERMOFORM SHEET MATERIALS AND ACCESSORIES

CLASSIFICATION NAME:	Sequential Aligner	NXC	872.5470
	Mouthguard	MQC	Unclassified
PREDICATE DEVICES:	Mouthguard and Aligner Materials		K062828

DEVICE DESCRIPTION: Thermoform Sheet Materials are flat sheets of thermoplastic. The sheets are heated by the practitioner and then vacuum-formed over a dental impression of the patient's teeth. The sheet is then trimmed to fit. The Accessories are sheet material formulations manufactured by injection molding.

INTENDED USE: Thermoform Sheet Materials and Accessories are indicated for the fabrication of orthodontic and dental appliances.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in Thermoform Materials and Accessories 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 Thermoform Sheet Materials and Accessories in legally marketed devices and the biocompatibility data provided support the safety and effectiveness of Thermoform Sheet Materials and Accessories for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

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

Re: K072522
Trade/Device Name: THERMOFORM SHEET MATERIALS AND ACCESSORIES
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MQC
Dated: September 6, 2007
Received: September 7, 2007

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. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072522

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K072522

Device Name: THERMOFORM SHEET MATERIALS AND ACCESSORIES

Indications for Use:

THERMOFORM SHEET MATERIALS AND ACCESSORIES are indicated for the fabrication of orthodontic and dental appliances.

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

Susan Runner

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

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