K080631

510(K) SUMMARY

Contact: Robert E. Tricca
Vice President, Operations
Oral Health Technologies, LLC
Tel: (925) 215-5452

MAY 23 2008

Date Prepared: February 20, 2008

First Device Trade Name: *Cleanse.Freshen.Go.* Aligner Cleansing Towelette

Common Name: Denture Cleanser

Classification Name: OTC Denture Cleanser (21 CFR 872.3520, Product Code EFT)

Legally Marketed Predicate Device: Efferdent Anti-Bacterial Denture Cleanser (Manufactured by Warner Lambert, a division of Johnson & Johnson).

Intended Use of First Device: *Cleanse.Freshen.Go.* Aligner Cleansing Towelette is intended for OTC use to clean oral debris from removable dental appliances after they have been removed from the mouth.

First Device Description: *Cleanse.Freshen.Go.* Aligner Cleansing Towelette is a cleansing solution impregnated onto a towelette for cleaning oral debris from removable dental appliances. It does not require dilution or activation and the pre-moistened towelette is supplied in compact and portable foil laminated hermetically sealed packages. The ready-to-use product form enables faster and more frequent cleansing of removable dental appliances in locations otherwise found to be impractical with many denture cleanser alternatives.

Second Device Name : *Cleanse.Freshen.Go.* Dental Appliance Cleanser

Common Name: Denture Cleanser

Classification Name: OTC Denture Cleanser (21 CFR 872.3520, Product Code EFT)

Legally Marketed Predicate Device: Efferdent Anti-Bacterial Denture Cleanser

Second Device Description: *Cleanse.Freshen.Go.* Dental Appliance Cleanser is a spray liquid cleansing solution for cleaning oral debris from removable dental appliances. It does not require dilution or activation and is supplied in a 2 oz. plastic pump spray bottle that is compact and portable. The ready-to-use product form enables faster and more frequent cleansing of removable dental appliances in locations otherwise found to be impractical with many denture cleanser alternatives.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Mr. Robert E. Tricca
Vice President Operations
Oral Health Technologies, LLC
1062 Allegheny Drive
Danville, California 94526

Re: K080631
Trade/Device Name: Cleanse.Freshen.Go. Aligner Cleansing Towelette
Cleanse.Freshen.Go. Dental Appliance Cleanser
Regulation Number: 21 CFR 872.3520
Regulation Name: OTC Denture Cleanser
Regulatory Class: I
Product Code: EFT
Dated: May 19, 2008
Received: May 22, 2008

Dear Mr. Tricca:

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.

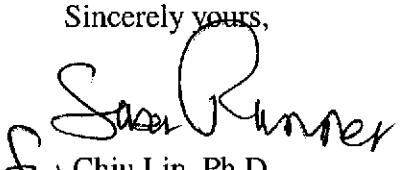
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



for 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

K080631

Indications for Use

510(k) Number (if known): Not known

Device Name: *Cleanse.Freshen.Go* Aligner Cleansing Towelette

Indications for Use: *Cleanse. Freshen. Go.* Aligner Cleansing Towelette is indicated for OTC use to remove oral debris and kill odor causing bacteria associated with removable dental appliances.

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

510(k) Number: K080631

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K080631

Indications for Use

510(k) Number (if known): Not known

Device Name: *Cleanse.Freshen.Go.* Dental Appliance Cleanser

Indications for Use: *Cleanse.Freshen.Go.* Dental Appliance Cleanser is indicated for OTC use to remove oral debris and kill odor causing bacteria associated with removable dental appliances.

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

510(k) Number: K080631

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)