OCT - 1 2001

HOMEDICS K012914

510(k) Summary Statement

Submission Date: May 4, 2001

Contact: David Vanderlin
Director of Engineering, Product Compliance
(248) 863-3000 ext. 1292 – tel.
(248) 863-3100 - fax

Classification Name: Toothbrush, Powered
Common/Usual Name: Sonic Toothbrush
Proprietary Name: SonicWave™ Sonic Plaque Remover HD-500
Classification: Class II

Description:

This 2.4 volt rechargeable battery operated toothbrush is a sonic wave plaque remover with rapidly vibrating bristles that penetrate the most difficult-to-clean areas of your mouth - Places your standard toothbrush might miss. It's also gentle, with seven speeds you can adjust to your own sensitivity level. This effective combination of ergonomics and technology brings you an easy, everyday way to prevent tooth decay and gum disease.

Intended Use:

- Operates at over 30,000 strokes per minute to help remove plaque bacteria.
- Sonic waves penetrate beyond the bristle tips, for superior cleaning.
- Ergonomic design with rubberized Comfort-Grip surface.
- Two-minute timer helps ensure dentist recommended brush time.

Substantial Equivalence Claim:

The SonicWave™ Sonic Plaque Remover is substantially equivalent to the current versions of the following model:

1. Sonicare Model TX-1 Sonic Toothbrush. K921773

Substantial equivalence is claimed because manufacturing technology, operating principles, intended uses and safety standards are the same for all models. Functional differences, i.e. seven speed levels, do not adversely affect safety or efficacy. Other differences are cosmetic in nature.

3000 Pontiac Trail
Commerce Township, MI 48390
Phone: (248) 863-3000
Fax (248) 863 - 3100

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 2001

Mr. David Vanderlin
Director of Engineering, Product Compliance
Homedics, Incorporated
3000 Pontiac Trail
Commerce Township, Michigan 48390

Re: K012914
Trade/Device Name: SonicWave™ Sonic Plaque Remover
Regulation Number: 872.6865
Regulation Name: Sonic Toothbrush
Regulatory Class: I
Product Code: JEQ
Dated: May 4, 2001
Received: August 30, 2001

Dear Mr. Vanderlin:

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 (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

Applicant: HoMedics, Inc.

510(k) Number (if known): K012914

Device Name: SonicWave™ Sonic Plaque Remover

Indications For Use:

- Operates at over 30,000 strokes per minute to help remove plaque bacteria
- Sonic waves penetrate beyond the bristle tips, for superior cleaning.
- Ergonomic design with rubberized Comfort-Grip surface.
- Two-minute timer helps ensure dentist recommended brush time.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Division Sign-Off)

Over-the-Counter Use ✓

510(k) Number K012914

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012914