K973424

DEC - 9 1997

510(k) SUMMARY

Enfresh's Tongue Brush

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Enfresh Products, LLC
12 Norcross Street
Suite 200C
Roswell, Georgia 30075

Contact Person:

Mr. Martin D. Crosson
Enfresh Products, LLC
Phone: (770) 594-2763
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Date Prepared: September 9, 1997

Name of Device

Enfresh Tongue Brush

Common or Usual Name

Tongue brush

Classification Name

Tongue brush

Predicate Devices

(1) Garry Laboratories's The Tongue Brush (K901408); and

(2) Telefax International's OOLI-U (Tongue Scraper) (K970042)

Intended Use

The Enfresh Tongue Brush and the predicate devices are intended to be used to remove plaque and food debris from the surface of the tongue. These devices are indicated for use several times a day, followed by rinsing the mouth and tongue with water.

Technological Characteristics and Substantial Equivalence

The Enfresh Tongue Brush and the predicate tongue brushes, tongue scrapers, and tongue cleaners have very similar principles of operation. They are all manual devices that are used by applying a brushing, scraping, or both brushing and scraping motion to the surface of the tongue to remove plaque and food debris from the surface of the tongue.

The Enfresh Tongue Brush and the predicate devices also have very similar technical characteristics. The handle and the bristles of the Enfresh Tongue Brush and Garry Laboratories's The Tongue Brush are composed of plastic, rubber, and nylon, while Telefax International's OOLI-U (Tongue Scraper) is composed of stainless steel. Both plastic and stainless steel are durable, biocompatible materials that have a long history of safe use in devices.

Summary Basis for the Finding of Substantial Equivalence

The safety and effectiveness of the Enfresh Tongue Brush is based on the long history of safe use of tongue brushes, tongue scrapers, tongue cleaners, as well as the safe use of manual toothbrushes. The Enfresh Tongue Brush has the same intended use and very similar principles of operation and technological characteristics as the predicate devices. Thus, the Enfresh Tongue Brush is substantially equivalent to the predicate devices, because the Enfresh Tongue Brush raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Enfresh Products, LLC
C/O Mr. Howard M. Holstein
Hogan & Hartson L.L.P.
Partner
Columbia Square
555 Thirteenth street,N.W.
Washington, DC 20004-1109

Re: K973424
Trade Name: Enfresh Tongue Brush
Regulatory Class: Unclassified
Product Code: LCN
Dated: September 9, 1997
Received: September 10, 1997

Dear Mr. Holstein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

Based on the labeling provided, it has been determined that the tongue cleanser sold with the tongue brush is regulated as cosmetic. However, if claims are made that constitute drug use, you must go to the Center for Drugs for further review.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP

regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): _____

Device Name: Enfresh Tongue Brush

Indications For Use:

To remove plaque and food debris from the surface of the tongue.

(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)