JAN 14 1999

K983683

510(K) SUMMARY

1. **Submitter:**

Unik Products, Inc.
Dr. Nathmal Tarfare, President
4786 Mount Vernon Blvd.
Hamburg, New York 14075

Contact:

Harry E. Werner, Esq.
Lipsitz, Green, *et al.*
42 Delaware Avenue
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Buffalo, New York 14202
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Date prepared: October 16, 1998

2. **Device Name:**

a. Trade Name: Unik Tongue Cleaner

b. Common/Usual Name: Tongue Cleaner or Tongue Scraper

c. Classification Name: Scraper, Tongue (per LCN)

3. **Predicate Device:**

a. Breath-So-Fresh Tongue Cleaner (K972644)

4. **Device Description:**

This is a device consisting of a molded polypropylene plastic handle, similar in appearance to that of a toothbrush, and a U-shaped loop end made of either polypropylene plastic or stainless steel. The device is used by placing the loop end at the back of the tongue and gently dragging it toward the front. The device is designed so that there are no sharp edges.

5. **Intended Use:**

The intended use of the Unik Tongue Cleaner is to remove bacteria from and prevent plaque build-up on the tongue to help fight bad breath and promote oral hygiene.

6. **Technological Characteristics:**

The Unik Tongue Cleaner is similar to the Breath-So-Fresh Tongue Cleaner (K972644) in that both employ a handle at one end and a loop at the other end which is used to gently scrape the tongue. The Unik Tongue Cleaner's loop end is U-shaped; the Breath-So-Fresh Tongue Cleaner's loop end is spoon shaped. The Breath-So-Fresh Tongue Cleaner is made entirely of plastic; the Unik Tongue Cleaner is made either of all plastic or a plastic handle with a stainless steel loop end.

The Unik Tongue Cleaner and the predicate device are used in the same fashion: the loop end of the device is placed on the back of the tongue and then gently dragged to the front of the tongue.

7. **Summary to support substantial equivalence:**

The Unik Tongue Cleaner employs the same principles as the predicate device to accomplish the same end: use of a generally U-shaped loop to gently scrape bacteria and plaque from the surface of the tongue. Because the Unik Tongue Cleaner has the same intended use as the predicate device, is similar in design and is used in the same manner as the predicate device, it introduces no new safety or effectiveness issues and is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1999

Unik Products, Incorporated
C/O Harry E. Werner, Esq.
Lipsitz, Green, *et al.*
42 Delaware Avnenue
Suite 300
Buffalo, New York 14202

Re: K983683
Trade Name: Unik Tongue Cleaner
Regulatory Class: Unclassified
Product Code: LCN
Dated: October 16, 1998
Received: October 20, 1998

Dear Mr. Werner:

This letter corrects our substantially equivalent letter of October 16, 1998 regarding the error that was made on the Statement of Indication for Use form.

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.

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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action.

In addition, the Food and Drug Administration (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 that 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 their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely,

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

510(k) Number (if known): K983683

Device Name: Unik Tongue Cleaner

Indications for Use:

The intended use of the Unik Tongue Cleaner is to remove bacteria from and prevent plaque build-up on the tongue to help fight bad breath and promote oral hygiene.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983683

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