

SEP 11 1997

K972644

**510 (K) Summary of Safety and Effectiveness
for
Breath-So-Fresh Tongue Cleaner**

International Dental Design Specialists, Inc.
829 Ninth Street, Imperial Beach, California 91932
Telephone: (619) 424-5115
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1) SUBMITTER:

Name: International Dental Design Specialists, Inc.
Address: 829 Ninth Street, Imperial Beach, CA 91932
Telephone: (619) 424-5115
Fax: (619) 424-5128
Contact Person: Clifford Yudelman
Date: July 11, 1997

2) NAME OF DEVICE:

Proprietary Name: Breath-So-Fresh Tongue Cleaner
Common/Usual Name: Tongue Scraper/Tongue Cleaner
Classification Name: Tongue Scraper

3) PREDICATE DEVICES:

"The Professional Tongue Cleaner" (K961660)
"Oolitt Tongue Cleaner" (K962941)

4) DESCRIPTION OF DEVICE

The Breath-So-Fresh tongue cleaner is molded to a modified "spoon-shape". One end of the tongue cleaner is a handle. The other end is shaped as the bowl of the spoon. The tongue cleaner is held as a spoon, except upside down. The end tip of the spoon end is mildly rippled but has no sharp edges. The total length of the Breath-So-Fresh tongue cleaner is seven inches long and the cleaner is one and one-fourth inches wide at the widest portion.

The Breath-So-Fresh tongue cleaner is composed of a hard white plastic, either a polycarbonate plastic or a plastic similar to polycarbonate. This plastic is flexible as well as durable and is well suited to dental applications. The tongue cleaner is designed so that there are no sharp edges to the plastic.

5) INTENDED USE

To remove bacterial plaque and food debris from the surface of the tongue, promoting clean mouth and fresher breath.

6) TECHNOLOGICAL CHARACTERISTICS

The shape of the Breath-So-Fresh Tongue Cleaner is similar to the predicate device, the Professional Tongue Cleaner (K961660) in that both have a sturdy handle at one end and a rounded portion for placement on the tongue on the other end. The Breath-So-Fresh Tongue Cleaner combines this design with another feature: a rippled cleaning edge. Both the Breath-So-Fresh and the Oolitt (K962941) tongue cleaners have a rippled edge to enhance tongue scraping.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 11 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Clifford Yudelman
International Dental Design Specialists, Incorporated
629 Ninth Street
Imperial Beach, California 91932

Re: K972644
Trade Name: Breath-So-Fresh Tongue Cleaner
Regulatory Class: Unclassified
Product Code: LCN
Dated: July 11, 1997
Received: July 15, 1997

Dear Mr. Yudelman:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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

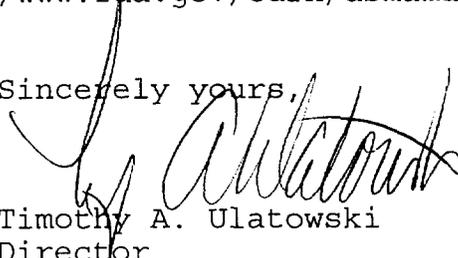
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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: Tongue Cleaner

Indications For Use:

To remove bacterial plaque and food debris from the surface of the tongue, promoting clean mouth and fresher breath.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rimmer
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K97216411

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓