SEP 23 1999

K992270

510(K) Summary
[As required by 21 CFR Section 807.92 (c)]

1. Contact Information

Submitter:	Stellar Labs, Inc.
Address:	5604 Marengo Road Bethesda, Maryland 20816
Telephone:	301.320.1217
Facsimile:	301.320.1217
Contact Person:	Harlan Pomeroy III
Telephone:	941.926.7745
Facsimile:	941.926.2512
Date Prepared:	Wednesday, June 30, 1999

2. Name of Device

Proprietary Name:	MiracleBreath Tongue Cleaner
Common Name:	Tongue Scraper/Tongue Cleaner
Classification Name:	Tongue Scraper

3. Predicate Devices

"Oolitt Tongue Cleaner" (K962941)

"Unik Tongue Cleaner" (K983683)

4. Description of Device

The device is a natural polypropylene band. It is formed into a u-shape by holding each end with the finger tips. The device is then placed on the back of the tongue and pulled forward gently with either the flat or rippled edge down. There are no sharp edges on the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

Mr. Harlan Pomeroy III
Senior Vice President
Stellar Labs, Incorporated
6637 Superior Avenue, Suite D
Sarasota, Florida 34231

Re: K992270
Trade Name: Miraclebreath Tongue Cleaner
Regulatory Class: Unclassified
Product Code: LCN
Dated: June 30, 1999
Received: July 6, 1999

Dear Mr. Pomeroy:

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, 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) 594-4690. 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,

Patricia Cucante/for

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

Enclosure

Figure 1

510(k) Number (if known):_____

Device Name: MiracleBreath Tongue Cleaner

Indications For Use:

To remove plaque and food debris from the surface of the tongue and to help fight bad breath and promote oral hygiene.

(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 K990270

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

(Optional Format 1-2-96)