

MAY 20 1998

K980842

## **510(k) Summary**

**Submitter:**

**Ontel Products Corporation**

2 Daniel Road East  
Fairfield, NJ 07004

**Contact person:**

**Mike K. Lakhiani**

2 Daniel Road East  
Fairfield, NJ 07004  
Phone: 973-227-6400  
Phone: 800-245-0511  
Fax: 973-227-8820

**Date Prepared:** March 2nd, 1998

**Name of Device:** Copper Tongue Scraper

**Common/Usual Name:** Tongue Scraper / Tongue Cleaner

**Classification Name:** Scraper, Tongue (per 76LCN)

**Predicate Device:** U.S. Dentek Sakool (K961574)  
Ooli-U Tongue Scraper (K970042)

**Description of Device:** This device is a U-formed design made of Copper.

**Intended Use:** This device is used to effectively remove bacteria and food debris from the surface of the tongue.

## **510(k) Summary**

**Technological Characteristics:** The Copper Tongue Scraper and the mentioned predicate devices all work in a similar fashion. They are all manual devices used to remove bacteria and food debris from the surface of the tongue by a gentle forward scraping motion. The Copper Tongue Scraper is composed of copper. Copper is biostatic, which means bacteria will not grow on its surface.

**Summary to support substantial equivalence:** The Copper Tongue Scraper's effectiveness is based on the long history of safe use of tongue scrapers. The Copper Tongue Scraper has the same design principals as the predicate devices. The only difference is that Copper Tongue Scraper is made from copper. Based on the characteristics and health benefits of copper, it is a safe material to use for this device. Therefore the Copper Tongue Scraper is substantially equivalent to the predicate devices because it raises no additional issues of safety and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 20 1998

Mr. Mike K. Lakhiani  
Vice President of Sales  
Ontel Products Corporation  
2 Daniel Road East  
Fairfield, New Jersey 07004

Re: K980842  
Trade Name: Copper Tongue Scraper  
Regulatory Class: Unclassified  
Product Code: LCN  
Dated: March 2, 1998  
Received: March 4, 1998

Dear Mr. Lakhiani:

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 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). 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.

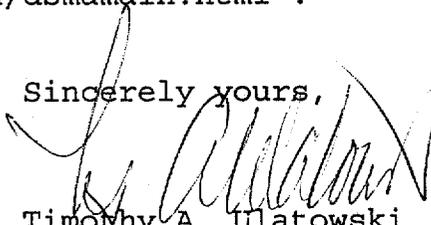
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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

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" (21CFR 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/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

510(k) Number (if known): \_\_\_\_\_

Device Name: COPPER TONGUE SCRAPER

Indications For Use:

Copper Tongue Scraper's intend use is to remove bacteria and food debris from the tongue surface, hence promoting good oral hygiene. It is intended for over-the-counter point of sale as are other predicate devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K180842

Prescription Use                        
(Per 21 CFR 801.109)

OR

Over-The-Counter Use                     

(Optional Format 1-2-96)