K032995

NOV 2 0 2003

6. 510(k) Summary of Safety and Effectiveness (revised)

510(k) number k032995

Air Scaler SSS

[As required by 21 CFR 807.87(h)]

6.1 Submitter Identification

Establishment:	Micron Corporation 1-34-14, Higashiyukigaya Ota-ku, Tokyo, 145-0065 Japan
Owner / Operator Number:	9037104
Establishment Registration Number:	9614726
Telephone Number:	+81-3-3726-0396
Fax Number:	+81-3-3726-5396
Official Correspondent:	Takashi Terui (Mr.)
E-mail Address:	terui@micdent.com
Date of Summary Preparation:	November 13th, 2003

6.2 Product Identification

Device Trade Name:	SSS
Classification Panel:	Dental
Classification Name:	Scaler Ultrasonic, per 21 CFR 872.4850
Common Name:	Air Scaler
Product Code:	ELC
Regulatory Class:	Class II

Models:
SSS 4H (with standard 4-hole coupling), product number 1072001
SSS 2H (with standard 2-hole coupling), product number 1072002

6.3 Identification of Legally Marketed Predicate Device

Device	Manufacturer	510(k) Number
Air scaler VIP 60	Micron Corporation	K991239

6.4 Device Description

As with its predicate device, SSS is an air scaler for use by dental professionals. The basic design of the predicate and modified devices are same: both are made in the shape of handpiece like dental turbines, used on a dental treatment unit and activated by compressed air delivered from the dental unit.

The common operation principle to the predicate is used in the modified device: When the compressed air runs into scaler's built-in vibratory cartridge, it generates elliptical movement of the scaling tip mounted.
The scaling tip movement removes dental calculus, plaque or stain from teeth.

6. 510(k) Summary of Safety and Effectiveness (revised)

510(k) number k032995

[As required by 21 CFR 807.87(h)]

Submitter/Manufacturer: Micron Corporation
1-34-14, Higashiyukigaya, Ota-ku,
Tokyo, 145-0065 JAPAN

Product name: Air scaler SSS

6.5 Indications for Use

SSS is intended for the applications below in the area of dental treatment by dental professionals.

- Removal of dental calculus, plaque or stain

6.6 Description of Modification

The running noise of SSS is substantially reduced by applying vibration frequency of 16,000 to 17,000 Hz for increased comfort of the user and patient, while the predicate device has frequency of 5,000 to 6,000 Hz and emits audible noise.
The vibration cartridge is redesigned so that the user can easily replace in his / her dental office.

6.7 Standards Met

1) ISO 15606 : 1999 — Dental handpieces -- Air-powered scalers and scaler tips
2) EN 1639 : 1996 — Dentistry — Medical devices for dentistry — Instruments
3) AAMI / ISO 14971-1 : 1998 — Medical Devices - Risk Management - Part 1: Application of risk analysis (General)

6.8 Summary of Design Control Activities

The risk analysis method to assess the impact of the modifications was based on a Failure Modes and Effects Analysis (FMEA).
This analysis built upon the risk analysis of the predicate device.

6.9 Substantial Equivalence Conclusion

The modified air scaler SSS has the following commonalities to its predicate device:

- the equivalent indication of use,
- the same operating principle applied,
- the same basic product design,
- conformity to the same and similar standards

Thus we believe the Micron SSS described in this submission has the substantial equivalence to the predicate device, submitter's VIP 60 air scaler.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Micron Corporation
Mr. Takashi Terui
Manager, Overseas Division
1-34-14, Higashiyukigaya
Ota-Ku, Tokyo, 145-0065 Japan

Re: K032995
Trade/Device Name: Air Scaler SSS
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: November 14, 2003
Received: November 17, 2003

Dear Mr. Terui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

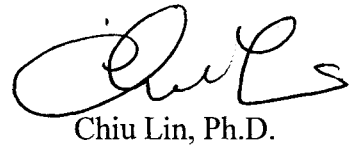
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032995

510(k) Number (if known): k032995

Device Name: Air scaler SSS

Indications For Use: This air scaler is intended to remove dental plaque, calculus and stain from tooth surface or root by dental professionals only.

Susan Runner

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

510(k) Number: K032995

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)