

OCT 18 1999

K991239

## 510(k) Summary

### Applicant:

MICRON CORPORATION  
1-34-14 Higashiyukigaya Ohta-ku,  
Tokyo 145-0065 JAPAN  
Tel: 81 3 3726 0396  
Fax: 81 3 3726 5396

Contact Person: Eiji Suzuki

### Date Summary Prepared:

April 06, 1999

### Classification Name:

Scaler Ultrasonic 21 CFR, 872.4850

### Common Name:

Air scaler

### Trade Name:

VIP 60

### Predicate Devices:

KAVO AMERICA'S SONICFLEX

## Intended Use

The VIP 60 is an instrument of calculus and plaque removal which the dentist uses for dental treatment.

This VIP 60 is used with scaling tips and a coolant water spray for debriding to heavy calculus and plaque deposits from tooth and root surfaces.

## Discription of Device

### Adavantages for patients

1. Much less pain as compared with ultrasonic scaling.
2. Less oppressive pain and less irritation to the tooth and gingiva.
3. Mush less bleeding
4. Post operative refreshness from pocket irrigation.

### Adavantages for operators

1. Direct connection to handpiece hose is possible.
2. Water spraying is minimum and working sites is clearly visible.
3. As the scaler tip is much more delicate (thin), subgingival pockets, interdental areas and molar furcations could be reached.
4. For the same reason, the feel of calculus adherence on the tooth can be transmitted to the operator's fingers, enabling careful and complete scaling even under indirect visualization.
5. Similarly, because delicate manipulation is possible, operator can avoid direct touching of hypersensitive areas of the tooth.

### Note

In using an ultrasonic scaler, it is indicated that the tip is favorably, kept at approximately 15 degrees during scaling in order to prevent injuring of the enamel.

In the case of VIP60 (air scaler), the tip can approach the calculus and the tooth surface in point contact which is more effective.

## Technological Characteristics and Substantial Equivalence

The general componets, design, characteristics, and mode of operation of the VIP60 and accessories are substantially Equivalent to Kavo America's SONICFLEX.

SONICflexLUX offers fiber optic illumination for maximum visibility in the scaling area.

SONIX flexLUX permits the removal of calculus and tartar by mechanical vibration.

Coolant water actually runs through and exits at the tip---where you need it.

Designed for repeated sterilization.



OCT 18 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Eiji Suzuki  
Micron Corporation  
1-34-14, Higashiyukigaya, Ohta-Ku  
Tokyo 145, Japan

Re: K991239  
Trade Name: VIP 60 (2H) Model 115-000-1 & VIP 60 (4H)  
Model 115-000-2  
Regulatory Class: II  
Product Code: ELC  
Dated: July 20, 1999  
Received: July 20, 1999

Dear Mr. Suzuki:

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

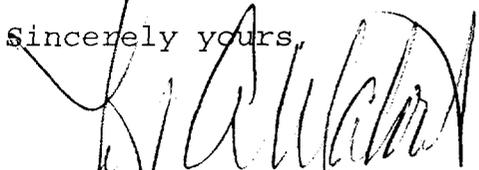
Page 2 - Mr. Suzuki

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" (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): K991239

Device Name: VIP 60 Model 115-000-1 and Model 115-000-2 (Sonic Scaler)

Indications For Use:

The VIP 60 is an instrument of calculus and plaque removal which the dentist uses for dental treatment. This VIP 60 is used with scaling tips and a coolant water spray for debriding heavy calculus and plaque deposits from tooth and root surfaces.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

**(Division Sign-Off)**  
**Division of Dental, Infection Control,**  
**and General Hospital Devices**  
510(k) Number K991239