DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 22, 2016

Micron Corporation
Takashi Terui
Sales Department Section Manager
2-17-7 Ikegami
Ota-ku, Tokyo, 146-0082
JAPAN

Re: K161639
Trade/Device Name: Y-MIC
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: June 10, 2016
Received: June 14, 2016

Dear Takashi 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Y-MIC

Indications for Use *(Describe)*
The proposed device is intended to remove plaque and calculus in the areas of dental scaling, and for use in periodontics, endodontics and prosthetic by dental professionals.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary (2nd revision)

807.92(a) (1) Sponsor / Submitter

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Contact Person: Takashi Terui (Mr.)
Date Prepared: September 27, 2016
510(k) Number: K161639/S001

807.92(a) (2) DEVICE

Name of Device: Y-MIC
Common or Usual Name: Dental air scaler
Classification Name: Ultrasonic scaler (21 CFR 872.4850)
Regulatory Class: II
Product Code: ELC

807.92(a) (3) PREDICATE DEVICE

Sybron Dental Specialties, Inc.
SONICflex 2003, K080089
No reference devices were used in this submission.

807.92(a) (4) DESCRIPTION OF DEVICE

The prosed device is used by dental professionals for removal of dental plaque and calculus, and for cleaning in periodontics, endodontics and prosthetics.

Both the predicate and the proposed devices are categorized in "Ultrasonic scaler" (FDA Product Code: ELC, Regulation No. 872.4850), but the both devices are not electric powered but air-driven same as air-powered dental handpieces (FDA Product Code: EFB, Regulation No. 872.4200).

To use the device, a hose from a dental unit that supplies the device with compressed air and water is attached to the back end of the device.

The compressed air is the energy source of the device to generate mechanical vibration.
Water from the dental unit is used for cooling and cleaning the treatment site.

When compressed air enters inside of the vibrator in the device, it generates mechanical vibration at the working tip attached to the front end of the device. The working tip contacts teeth and in certain cases, gum of the patient.
The removal of plaque and calculus or cleaning is performed by utilizing the vibration.
The device consists of the handpiece, connection to a hose and working tips.

The associated accessories include:
- tips for removal of plaque and calculus
- holder tips to attach endodontics files or tooth cleaning brushes
- tooth cleaning brushes
- tip replacement wrench

The proposed device and accessories are supplied non-sterile and must be sterilized in an autoclave prior to the first use by the end-user.

807.92(a) (5) INTENDED USE
The proposed device is intended to remove plaque and calculus in the areas of dental scaling, and for use in periodontics, endodontics and prosthetic by dental professionals.

807.92(a) (6) COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

	Proposed device	Predicate device
Product name	Y-MIC	SONICflex 2003
510(k) number	K161639/A001	K080089
Manufacturer / submitter	Micron Corporation	Sybron Dental Specialties
Device type	Dental air scaler	Dental air scaler
Energy source	Compressed air supplied from a dental unit.	Compressed air supplied from a dental unit.
Design	Connects to hose of a dental units.	Connects to hose of a dental units.
Performance	Output frequency about 6,000 Hz.	Output frequency about 6,000 Hz.
Target population	Dental patients.	Dental patients.
Where used	Dental offices or clinics.	Dental offices or clinics.
Human factor	Used by trained dental professionals.	Used by trained dental professionals.
Sterile or non-sterile	Supplied non-sterile.	Supplied non-sterile.

Electrical safety and EMC	An air-driven device. N/A	An air-driven device but the model with illumination may be applicable.
Software	Not incorporated.	Not incorporated.

Vibration generated by compressed air supplied from a dental unit is the operating principle for both the proposed and predicate devices.
Both the proposed and predicate devices connect to the hose of the dental unit that supplies the devices with compressed air via the connectors at the rear end of the devices.
Dental treatment with the devices is performed by use of this vibration.

At a high level, the predicate and predicate devices are based on the same technological elements below:
- Energy source – compressed air supplied from a dental unit
- No use of electricity as energy source
- Creation of mechanical vibration by utilizing the compressed air
- Use of the mechanical vibration to achieve the treatment effect
- Frequency output of the vibration about 6,000 Hz
- Working tips attached to the front end
- Connector located at the rear end to connect to the dental unit
- Handpiece design like dental handpieces
- No use of software to activate and/or control the devices

However, though the predicate has a model with fiber-optic illumination, the proposed device has not yet.

807.92(b) (1) NON CLINICAL TESTS

* General
The proposed device was evaluated in accordance with elements of applicable international standards for medical devices in which the proposed device is categorized (dental air scaler).
Compliance tests included evaluation of basic safety and requirements, risk management, biological evaluation and reprocessing of medical devices. The device passed all of the compliance tests.
Although the standards applied to the predicate are not known to the submitter, but because both the proposed and predicate devices are dental devices of the same sort, the submitter believes the applicable standards to the predicate should be same as and common to those applicable to the proposed device at a high level.

* Performance test

The proposed device was evaluated for device performance features including frequency output, amplitude, resistance to autoclave sterilization and corrosion. The device passed all of the performance criteria.

* Electrical safety and electromagnetic compatibility (EMC)

The proposed device is not electric-powered but air-driven like the predicate device.
It is not subject to the IEC 60601 standards and no testing for electrical safety or EMC according to these standards were performed.

* Software

The proposed device is not software-controlled and incorporates no software like the predicate device.
The proposed device has no concern about software.

807.92(b) (2) CLINICAL TESTS

Not applicable, no changes in indication for use.

807.92(b) (3) CONCLUSIONS

The proposed device is operated utilizing the same operating principle and used to the same intended use as the predicate device.
The non-clinical data support that the proposed device performs as intended and conforms to the applicable standards.
Thus the submitter believes the information submitted demonstrates that the proposed device is substantially equivalent to the predicate device.