K133170

MAR 2 8 2014

5.510(k) Summary

5.1 SPONSOR / SUBMITTER

a. Company name: MICRON Corporation

b. Address: 1-34-14, Higashiyukigaya, Ota-ku, Tokyo, 145-0065, Japan

c. Contact person: Takashi Terui (Mr.)

d. Phone number: +81-3-3755-0396

f. Fax number: +81-3-5747-5396

g. E-mail address: office@micdent.com

Date Prepared

11/08/2013

510(k) Number: K133170

5.2 DEVICE NAME

Trade/Proprietary Name:

QUICK JET M

Device Classification / Classification Panel

a. Common / Usual Name: Dental Handpiece

b. Classification Name: Dental Handpiece and Accessories

c. Regulation Number: 21 CFR 872.4200

d. Regulatory Class: I

e. Product Code: EFB

5.3 PREDICATE DEVICE

Name of the Manufacturer or Specification developer	Product name	510(k) Number	Classification Product Code	Classification Name
E.M.S. Electro Medical Systems S.A.	AIR-FLOW handy 2	K022119	EFB	Dental handpiece and Accessories

5.4 DEVICE DESCRIPTION AND INTENDED USE

Device Description

Both the predicate and the new proposed devices are operated by connecting to a standard turbine connection of a dental unit, which supplies air and water. The device is activated when the dental unit is activated and compressed air and water are supplied to the device.

Air enters into the powder chamber where it is mixed with the prophylaxis powder.

Micron Corporation, 510(k) Summary

The mixture of air and water leaves the powder chamber and exits the distal end of the device through the spraying nozzle where the mixture of air and water is enveloped by water spray and directed onto the tooth surface. The mixture of air, water and powder removes dental plaque, stain and discoloration from tooth surface.

Intended Use

The proposed device is intended to remove dental plaque, stain, and discoloration from tooth surface etc. by dental professionals during dental treatment

5.5 SUBSTANTIAL EQUIVALENCE

Technological Characteristics of Handpiece	Comparison result
	AIR-FLOW handy 2
intended use	Slimilar
Indication for use	Identical
Target population	Identical
Anatomical safety	Identical
Where used(hospital, home, ambulance, etc)	Identical
Engery used and/or delivered	Identical
Human factors	Identical
Design	Slimilar
Performance	Slimilar
Standards met	Unknown
Materials	Slimilar
Biocompatibility	Unknown
Compatibility with environment and other devices	Identical
Sterility	Slimilar
Electrical safety	N/A
Mechanical safety	Identical
Chemical safety	Slimilar
Thermal safety	N/A
Radiation safety	N/A

5.6 SUMMARY OF NON-CLINICAL TESTING

The proposed device was designed and tested according to the applicable international standards and specifications developed by the manufacturer.

5.7 SUMMARY OF CLINICAL TESTING

No clinical tests were performed for the proposed device device.

5.8 CONCLUSION

The information above demonstrates that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

MICRON Corporation
Mr. Takashi Terui
1-34-14, Higashiyukigaya
OTA-Ku, Tokyo 145-0065
Japan

Re: K133170
Trade/Device Name: Quick Jet M
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: December 26, 2013
Received: January 2, 2014

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. 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.

If 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): Not Assigned

Device Name: Quick Jet M

Indications for Use:

The product is intended to remove dental plaque, stain, and discoloration from tooth surface etc. by dental professionals during dental treatment..

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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Sheena A. Green -S
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