JUN 2 4 1999

K991035

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: March 1999

Device Name:

- Trade Name - Quantec-E Irrigation System
- Common Name - Fluid Delivery Unit
- Classification Name - Dental Handpiece and Accessories, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- Micro Motors, Inc., *Micro SWP Sterile Water Pump*

Device Description:

The device is a self-contained, fluid delivery unit consisting of a pump console, two irrigation reservoirs and tubing intended to be used in dentistry to provide irrigation while using the dental handpieces attached to the Quantec-E Endo System. The unit attaches to the Quantec-E Endo System via the accessory port located on the rear panel of the unit. The Quantec-E Irrigation System cannot operate as a stand alone device. The unit has a positive displacement peristaltic design to prevent fluid retraction which could result in patient cross-contamination. To operate the Quantec-E Endo System without irrigation, the Power Switch on the Quantec-E Irrigation System console is turned to the "O" position. When irrigation is desired, the switch is turned to "I". The irrigation tip assemblies supplied with the Quantec-E Irrigation System is autoclavable.

Intended Use of the Device:

The intended use of the Quantec-E Irrigation System is to provide irrigation while using the dental handpieces attached to Quantec-E Endo System.

Substantial Equivalence:

The Quantec-E Irrigation System is substantially equivalent to several other legally marketed devices in the United States. The Quantec-E Irrigation System functions in a manner similar to and is intended for the same use as the Micro SWP Sterile Water Pump designed by Micro Motors, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1999

Ms. Colleen Boswell
Manager, Regulatory Affairs
Syborn Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K991035
Trade Name: Quantec-E Irrigation System
Regulatory Class: I
Product Code: EIA
Dated: March 24, 1999
Received: March 29, 1999

Dear Ms. Boswell:

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 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

Section I - Indications for Use

510(k) Number: _____

Device Name: Quantec-E Irrigation System

Indications for Use:

The Quantec-E Irrigation System is a self-contained, fluid delivery unit consisting of a pump unit console, irrigation reservoirs and tubing intended to be used in dentistry to provide irrigation while using the dental handpieces attached to the Quantec-E Endo System.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991625