APR 30 1998

SYBRON
DENTAL SPECIALTIES, INC.

K981023

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7425 - Phone
(714) 516-7488 - Facsimile
Wendy A. Urtel - Contact Person

Date Summary Prepared: March 1998

Device Name:

- Trade Name - **Kleenaseptic**
- Common Name - General Purpose Disinfectant
- Classification Name - Unclassified

Device Description:

Kleenaseptic is a ready-to-use, spray-on isopropyl alcohol/quaternary ammonium general purpose disinfectant used for the cleaning and disinfection of equipment surfaces and non-critical devices prior to terminal sterilization/high-level disinfection in healthcare environments.

Intended Use of the Device:

Kleenaseptic is a general purpose disinfectant intended for use in cleaning and disinfecting equipment surfaces and non-critical devices in hospitals and other critical care areas where environmental control of cross contamination is important.

Kleenaseptic is a disinfectant when used on equipment surfaces and non-critical devices for 10 minutes at room temperature (69°F/20°C).

Substantial Equivalence:

The basis for determination of substantial equivalence for Kleenaseptic, a general purpose disinfectant, is its EPA registration as demonstrated by the assignment of EPA registration number 46781-7 and the EPA-stamped approved label.

This submission is in conformance with the FDA "Guidance on the Content and Format of 510(k) Submission for General Purpose Disinfectants", October 1993. The Guidance allows for a 510(k) in order to carry out the intent of the Memorandum of Understanding (MOU) between the EPA and FDA dated June 4, 1993 and amended June 2, 1994. The MOU is an interim agreement between the two agencies regulating the same products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Metrex Research Corporation
C/O Ms. Wendy A. Urtel
Regulatory Affairs Specialist
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92667

Re: K981023
Trade Name: Kleenaseptic
Regulatory Class: Unclassified
Product Code: LRJ
Dated: March 17, 1998
Received: March 19, 1998

Dear Ms. Urtel:

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

Indications for Use

510(k) Number: K981023

Device Name: Kleenaseptic

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Kleenaseptic is a disinfectant when used on equipment surfaces and non-critical devices for 10 minutes at room temperature (69°F/20°C).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981023

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)