JUL 14 1999

510 K Summary
K 991509

Physical Characteristics

Product designation:	*A phenolic cleaner/disinfectant*
Appearance (concentrate):	*Clear light amber liquid*
Odor:	*Slight alcohol*
Percent of Phenolics:	*Concentrate 10.5%*
pH (concentrate):	*9.1 – 11.1*
pH (use-dilution):	*6.8 – 8.2*
Specific Gravity (25°C):	*.9-1.1*
Flash Point:	*None*
Detergency:	*Excellent*
Phosphate Content:	*None*

TÜV CERT ISO 9001 REGISTERED
OSAP
Sultan Chemists, Inc.
85 West Forest Ave., Englewood, NJ 07631
Phone: (201) 871-1232 • Toll Free: (800) 637-8582
Fax: (201) 871-0321 • http://www.sultanintl.com
DMA
ADCA

510 K Summary
K 991509

Submitter: Sultan Chemists
85 W. Forest Avenue
Englewood, NJ 07631

Contact Person: Les Heimann

Date Prepared: June 16, 1999

Propriety Name: Pro-Portion ™ cleaner/ disinfectant

Common Usual Name: General Purpose Cleaner/ Disinfectant

Disinfectant Category: Intermediate level

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection. To be effective a ten-minute contact time at room temperature (69°F / 20°C) is required.

Use, Functions, Concepts, and Performance Characteristics

Pro-Portion is a broad spectrum, multi-purpose ready to use, effective cleaner and disinfectant for use on the surfaces of inanimate objects. Pro-portion will efficiently clean and disinfect, when used as directed, such items as laminated counter tops, dental units, dental instruments, lights, and other inanimate surfaces, including those made of plastics (such as: polycarbonate, polyvinylchloride, polypropylene and polystyrene), nonporous vinyl and upholstery, stainless steel, painted surfaces, Plexiglas, glass, and other hard non-porous surfaces.

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DMA ADA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Mr. Les Heimann
Vice President of Quality
Sultan Chemists, Incorporated
85 West Forest Avenue
Englewood, NJ 07631

Re: K991509
Trade Name: Pro-Portion™ Cleaner/Disinfectant
Regulatory Class: Unclassified
Product Code: LRJ
Dated: April 24, 1999
Received: April 30,1999

Dear Mr. Heimann:

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

510(k) Number (if known): K991509

Device Name: Pro-Portion™

Indications For Use:

Pro-Portion is a general-purpose cleaner/disinfectant. Its use is restricted to a health care setting where low and intermediate level disinfection of hard, non-porous surfaces is required. It is intended to be used in a dental office as an instrument ultrasonic cleaning solution. In order to disinfect, a contact time of 10 minutes at 69°F / 20°C is required.

This product may be used to pre-clean or decontaminate of critical or non-critical medical devices prior to sterilization. Must be followed by appropriate terminal sterilization or high-level disinfection process.

(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 K991509

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

(Optional Format 1-2-96)