

DEC 4 1998

510(k) Summary

K98 3947

Trade Name: Amerse 2

Common/Usual Name: General Purpose Disinfectant

Submitter/Manufacturer: STERIS Corp.
5035 Manchester Avenue
St. Louis, MO 63110
Establishment Registration Number: 1940768

Contact: Mike Ebers, Manager Regulatory Affairs (314) 535-1390

Description: Amerse 2 is a liquid chemical germicide concentrate utilizing phenolic compounds as active ingredients.

Intended Use: Amerse 2 is used to inactivate specific bacteria, fungi and viruses on hard inanimate surfaces including reusable non-critical medical devices and environmental surfaces in healthcare facilities with a 10 minute contact time at 20°C by housekeeping, nurses, and emergency medical personnel.

Substantial Equivalence to: (1) Bulk Lysol® Brand Disinfectant, (2) LF-10 Hospital Disinfectant Concentrate, Reckitt & Coleman (3) Micro Bac Phenolic Detergent Disinfectant, Ecolabs and (4) Sporicidin Brand Disinfectant Solution, Sporicidin International.

Comparison to Listed Substantially Equivalent Products: Listed products are also liquid chemical germicides utilizing phenolic compounds as active ingredients to inactivate specific bacteria, fungi, and viruses on hard inanimate surfaces.

Safety Data: Acute Oral LD₅₀ (Rats) = 4,500 mg/kg
Acute Inhalation LC₅₀ (Rats) > 54.3 mg/l
Dermal Irritation (Rabbit) = The product tested neat was corrosive to the skin. At a 1:128 dilution the product showed a Primary Irritation Index of 1.10 (Draize Scale), Slight Irritation
Eye Irritation (Rabbit) = At a 1:128 dilution showed irritation reversible within 7 days.

Effectiveness Data: Germicidal: Passes AOAC Germicidal Use-Dilution Test against *S. aureus*, *S. choleraesuis*, *Ps. aeruginosa* and other bacteria.
Tuberculocidal: Passes AOAC Tuberculocidal Test.
Fungicidal: Passes AOAC Fungicidal Test against *T. mentagrophytes* and other fungi.
Virucidal: Passes Virucidal Qualification Test against Influenza A₂ (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine Pseudorabies
Passes EPA approved Dilution Method against the HIV-1 (AIDS) virus.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael G. Sarli
Regulatory Specialist
Steris Corporation
5035 Manchester Avenue
St. Louis. Missouri 63110

Re: K983947
Trade Name: Amerse 2
Regulatory Class: Unclassified
Product Code: LRJ
Dated: November 2, 1998
Received: November 5, 1998

Dear Mr. Sarli:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

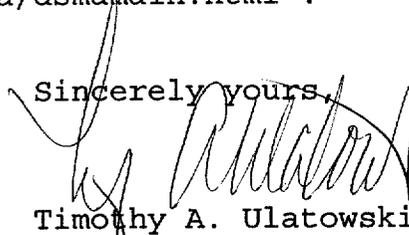
Page 2 - Mr. Sarli

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" (21CFR 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/dsma/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): K983947

Device Name: Amerse 2

Indications For Use: Amerse 2 is a general purpose disinfectant used to reprocess noncritical devices and medical equipment surfaces and to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection with a 10 minute contact time at 20°C.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K983947

Prescription Use _____
(per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)