

## 510(k) Summary

K974304

JAN 13 1998

**Trade Name:** Germicidal Cloth

**Common/Usual Name:** General Purpose Disinfectant

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

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

**Description:** Germicidal Cloth is a liquid chemical germicide saturated, disposable cloth utilizing quaternary ammonium chloride compounds as active ingredients.

**Intended Use:** Germicidal Cloth 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.

**Substantial Equivalence to:** (1) Tor Germicidal Cleaner, Huntington Laboratories, (2) Quat-Syl 256, National Laboratories, (3) Futron 25, Hysan Corp.

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

**Safety Data:** Acute Oral LD<sub>50</sub> (Rats) = 5,000 mg/kg

Acute Dermal LD<sub>50</sub> = > 2,000 mg/kg

Dermal Irritation (Rabbit) neat = Produced mild transient redness and swelling

Eye Irritation (Rabbit) neat = Produced mild transient eye irritation.

Dermal Sensitization (Guinea Pig) = Negative as sensitizer

**Effectiveness Data:** Germicidal: Approved by EPA against *S. aureus*, *S. choleraesuis* and *Ps. aeruginosa* and other bacteria.

Tuberculocidal: Approved by EPA against *Mycobacterium bovis* (BCG)

Fungicidal: Approved by EPA against pathogenic fungi

Virucidal: Approved by EPA against Adenovirus Type 5, Canine Distemper, Herpes simplex Type 2 Virus, HIV-1, Influenza A<sub>2</sub>/HK Virus, Pseudorabies Virus, and Vaccinia Virus.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Michael Ebers  
Manager Regulatory Affairs  
STERIS Corporation  
Calgon Vestal Division  
5035 Manchester Avenue  
St. Louis, Missouri 63110

JAN 13 1998

Re: K974304  
Trade Name: Germicidal Cloth  
Regulatory Class: Unclassified  
Product Code: LRJ  
Dated: November 11, 1997  
Received: November 17, 1997

Dear Mr. Ebers:

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.

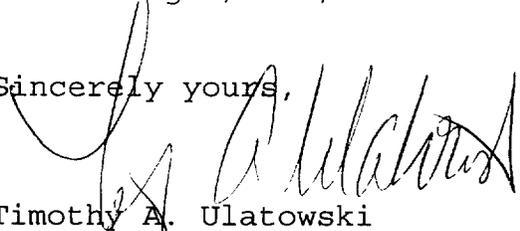
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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 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) 594-4618. 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

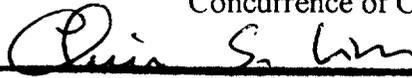
510(k) Number (if known):

Device Name: Germicidal Cloth

Indications For Use: Germicidal Cloth is a general purpose disinfectant used to reprocess noncritical devices and medical equipment surfaces.

(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 K 074304

Prescription Use \_\_\_\_\_  
(per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)