MAY 3 1 2000

510(k) SUMMARY K983068

This pre-market notification was submitted by the following individual:

Raymond Ursick,
Vice-President, Regulatory Affairs and Quality Systems
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060
Tel: 440-354-2600

This 510(k) summary was prepared on May 12, 2000.

Device identification	
Trade name	Amsco® Reliance® Family of Washer/Disinfectors
Common name	Washer/Disinfector
Classification	II (As recommended by classification panel)

Predicate devices		
Name	Model 7550 Washer/Disinfector	T-21 Decontaminating Machine
Manufacturer	MDT/Castle	HAMO, USA, Inc.
Classification	NOT CLASSIFIED	NOT CLASSIFIED
510(k) number	K911087	K911120

DEVICE DESCRIPTION

The Amsco Reliance Family of Washer/Disinfectors are mechanical, computer-controlled Washer/Disinfectors. They are designed with pre-programmed cycles intended specifically for surgical instruments, delicate instrumentation (gentle cycle), utensils, glassware, plastic goods, anesthesia/respiratory goods and equipment decontamination. Additional cycles are available for customized programming to meet specific operating requirements.

Essentially, the Amsco Reliance Family of Washer/Disinfectors operate as follows: the load items are placed in the chamber where they are exposed to pressurized fluids delivered through a circulation system driven by a pump and controlled by a programmable computer. Injection pumps allow the automatic delivery of the selected

chemicals in the sump water. Available configurations include steam or electrical heating of the sump water; and the drying option (electrically heated on some models, steam heated on others). The cabinet, chamber, and circulation system (including the pump) are primarily constructed of stainless steel.

The available cycle phases can be summarized as follows:

1. cold tap water pre-wash for the removal of gross soil;
2. soaking in an enzymatic solution to break down proteinaceous materials;
3. detergent wash to complete the soil removal;
4. sonic cleaning to remove fine debris in crevices;
5. hot tap water rinse to remove detergent and soil residues;
6. thermal rinse to disinfect the load items;
7. pure water rinse and instrument lubrication;
8. drying.

Note: Phases 2 and 4 are not offered on all models.
Phases 2, 4, 7 and 8 are optional features.

The available accessories include a variety of single and multi-level loading racks, and transfer carts. Some models offer conveyor systems used to automate the loading of racks into the chamber, to initiate the proper cycle by reading a bar code tag located on the loading rack, and to provide queuing capacity.

INTENDED USE

The Amsco Reliance Family of Washer/Disinfectors are indicated for use in the cleaning and low-level disinfection of soiled reusable utensils, trays, glassware, bedpans and urinals, rubber and plastic goods, simple hard-surfaced rigid surgical instruments such as forceps and clamps, and other similar and related articles found in healthcare facilities.

SUBSTANTIAL EQUIVALENCE - TECHNOLOGICAL COMPARISON

In most respects, including intended use, operating principle, energy sources, construction materials and control technology, the Amsco Reliance Family of Washer/Disinfectors are quite similar to both predicate devices. All use impingement and chemical means to remove soil, contaminants and residues from used medical devices and provide hot water thermal disinfection, in order to render them safe for handling and further processing by healthcare facility personnel. The devices are constructed primarily of stainless steel with rotating spray arms in a closed chamber. Hot water and detergents are circulated in varying cycles, in order to wash and disinfect a variety of medical devices approved for reuse. Microprocessors are used to provide cycle control.

There is a notable difference in the cycle parameters structure, which is attributable to the fact that the MDT/Castle predicate device uses the wash phase to accomplish the thermal disinfection whereas the HAMO and Amsco Reliance Family of Washer/ Disinfectors uses the thermal rinse phase. Additionally, the MDT/Castle device has a high-level disinfection claim which requires a longer thermal disinfection phase time. The Amsco Reliance Family of Washer/Disinfectors disinfection claim is restricted to low-level disinfection, based on the understanding that this level is suitable for contact with intact skin, and therefore compatible with the safe handling of processed items by healthcare facility staff.

PERFORMANCE TESTS - TEST SCHEME DESCRIPTION

In order to demonstrate the actual performance levels achieved by the Amsco Reliance Family of Washer/Disinfectors, a series of simulated-use type-tests have been conducted. These included assessment of the cleaning, rinsing of residues and (thermal) disinfection efficiencies, in representative conditions. The areas of the machine and accessories that could potentially be colonized by heterotrophic microorganisms have been submitted to a biofilm challenge test to prove that the recommended equipment decontamination procedures are effective to prevent any bacterial growth inside the unit. Finally, a full-strength immersion test was conducted to demonstrate that the practice of applying instrument lubricant on hinged surgical instruments during the final rinse phase will not interfere with subsequent sterilization.

TEST RESULTS - CLEANING

Side-by-side testing was performed with the HAMO device to verify the Amsco Reliance Family of Washer/Disinfector's ability to clean a representative load. The test method consisted of covering test items with blood based representative soil, and performing a visual inspection of items after processing to determine the presence of visible residual soil. It was shown that the Amsco Reliance Family of Washer/Disinfectors provided substantially equivalent or better cleaning performance when used as directed.

TEST RESULTS - RESIDUES

Testing was performed to establish the efficacy of the rinse phases to remove detergent and enzymatic residues on load items to levels known to be non-toxic to patients and users. The test method consisted of measuring the conductivity increase of test solution caused by the elution of ionic detergent residues left on test items to determine the quantities of residues. The non-ionic enzymatic residue levels were measured by colorimetric evaluation method and by conductivity increase. The following table shows

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the acceptance criteria and results for each item family and chemical tested.

Chemical	Items	Acceptance Criteria (mg/item)	Results (mg/item)[1]
STERIS Liqui Jet	Surgical Instruments	0.79	0.023
	Micro Surgery Instruments	0.79	0.069
	Suction Tips	6.34	0.08
	Respiratory Equipment	12.66	4.1
Enzy Care II (detergent fraction)	Surgical Instruments	4.8	0.11
	Micro Surgery Instruments	4.8	0.4
	Suction Tips	9.5	0.31
Enzy Care II (enzyme fraction)	Surgical Instruments	14.5	<0.8
	Micro Surgery Instruments	14.5	<3.9
	Suction Tips	29	<3.7
Descaler	Surgical Instruments	2.9	0.016
	Micro Surgery Instruments	2.9	0.016
	Suction Tips	5.8	0.016
	Respiratory Equipment	46.4	0.016
NpH-Klenz®	Rigid MIS Instruments	2.8	0.26[2]
Klenzyme® (detergent Fraction)	Rigid MIS Instruments	7.7	0.63[2]
Klenzyme® (enzyme fraction)	Rigid MIS Instruments	15.5	<0.27[2]

Note 1: Test results as obtained with the Amsco Reliance 444 Single-Chamber Washer/Disinfector, and are considered as representative of the results obtained for the Family of Washer/Disinfectors.
Note 2: The MIS rack only applies to the Amsco Reliance 444 Single-Chamber Washer/Disinfector.

TEST RESULTS - THERMAL LOW-LEVEL DISINFECTION

Challenge testing was performed to verify the ability of the Amsco Reliance Family of Washer/Disinfectors to achieve low-level disinfection of commonly processed items. The test method consisted of placing vials containing known concentrations of microorganisms in the coldest areas of the chamber and measuring logarithmic reductions after processing through the thermal rinse treatment.

A sample test conducted with the MIS rack on the Amsco Reliance 444 Single-Chamber Washer/Disinfector, using microorganisms recognized as suitable to test low-level disinfection, demonstrated that greater than 8 logarithmic reductions of the test organisms was achieved.

TEST RESULTS - EQUIPMENT DECONTAMINATION

Testing was performed to validate that the equipment decontamination procedures in the device labeling are effective to prevent the formation of biofilm or growth of heterotrophic microorganisms in critical areas of the device.

The test method consisted of operating the Washer/Disinfector with various loading racks for 3 consecutive weeks and, on a weekly basis, swabbing the surfaces of critical areas of the machine and loading racks, and culturing to detect the presence of biofilm

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formation.

The test reports conclude that in its current design, the Washer/Disinfector and its accessories, when submitted to the recommended decontamination procedure, are not likely to develop biofilm on identified critical areas.

TEST RESULTS - INSTRUMENT LUBRICATION

Testing was performed to verify that the process of lubricating an item prior to terminal processing did not affect the item's ability to be sterilized.

The test method consisted of inoculating hinged instruments with bacterial spores, dipping them into full strength instrument lubricant before sterilization and testing them for sterility.

The test report shows that no growth could be detected on any of the lubricated as well as unlubricated instruments, demonstrating that the practice of lubricating instruments in the Washer/Disinfector at any concentration will not impede the ability to sterilize them subsequently.

CONCLUSIONS

Whereas, the test conditions were designed to be representative conditions within the intended use of the Washer/Disinfector;

Whereas, these tests have been conducted in keeping with applicable quality systems regulations (Good Laboratory Practice, 21CFR §58), whether conducted in STERIS facilities or subcontracted;

Whereas, per STERIS Corporation's intent, the above mentioned test conditions were designed to be adequate, complete and challenging to all aspects relating to the performance, safety and effectiveness of the device for its intended use;

STERIS Corporation considers the Amsco Reliance Family of Washer/Disinfectors to be safe, effective, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 1 2000

Mr. Raymond Ursick
Vice-President, Regulatory Affairs and Quality Systems
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

Re: K983068
Trade Name: Amsco® Reliance Family of Washer-Disinfectors
Regulatory Class: Unclassified
Product Code: LDS
Dated: March 20, 2000
Received: March 21, 2000

Dear Mr. Ursick:

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,

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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STERIS Amsco Reliance Family of Washer / Disinfectors

INDICATIONS FOR USE STATEMENT

DEVICE NAME: STERIS Amsco Reliance Family of Washer / Disinfectors

INDICATIONS FOR USE:

The STERIS Amsco Reliance Family of Washer / Disinfectors are indicated for use in the cleaning and low-level disinfection of soiled reusable utensils, trays, glassware, bedpans and urinals, rubber and plastic goods, simple hard-surfaced rigid instruments such as forceps and clamp, and other similar and related articles found in healthcare facilities.

(Please Do Not Write Below This Line - Continue on Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Chun S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983068