

12/3/99

K991575

Reference: 21 CFR, Part 807.87(h) Information required in a premarket notification submission.

(h) A 510(k) summary as described in Sec. 807.92 or a 510(k) statement as described in Sec. 807.93.

A 510(K) SUMMARY PERTAINING TO THE SAFETY AND EFFECTIVENESS OF THE PRIMUS PSS SERIES STERILIZER

Manufacturer: PRIMUS Sterilizer Co., Inc.
117 South 25th Street
Omaha, NE 68131
Phone: 402-344-4200
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Contact: Jeff Reed, Engineering Manager

Date Prepared: May 3, 1999

Introduction

The PRIMUS PSS series steam sterilizers are class II medical devices as defined by 21 CFR 880.6880. The PSS series sterilizers feature fully jacketed, rectangular 316L stainless steel chambers with sliding doors. The units are available in Multifunction or Laboratory/Lo configurations. The Multifunction units offer both prevacuum and gravity configurations, whereas the Laboratory/Lo units offer prevacuum, gravity, and a low operating temperature configuration.

The PRIMUS PSS series sterilizers are offered for sale with the following factory-set sterilization cycles and cycle values:

CYCLES	STERILIZE TEMP	STERILIZE TIME	DRY TIME	RECOMMENDED LOAD
GRAVITY	132° C	4 MINUTES	1 MINUTE	HARD GOODS
VACUUM	132° C	4 MINUTES	15 MINUTES	WRAPPED GOODS
LIQUIDS	121° C	30 MINUTES	*8 MINUTES	LIQUIDS
TEST (VAC)	132° C	4 MINUTES	3 MINUTES	BOWIE-DICK TEST

*Liquid Cycle is Cool Time

Validation

Evaluation of the sterilizer function and exposure time recommendations has been completed to validate the safety and effectiveness of the PRIMUS PSS series

sterilizer. The test plan was derived from AAMI ST8 1994 Volume 1. All tests were performed satisfactory showing complete kill of biological indicators with appropriate sterility assurance level of less than 10^{-6} .

Results of the validation studies conducted demonstrate the sterilizers perform as intended with the results shown below:

- Compliance to AAMI ST8-1994. This standard establishes the minimum performance for hospital sterilizers that use saturated steam as the sterilizing agent. The standard is applicable for sterilizers with a volume greater than two cubic feet. The PRIMUS PSS series sterilizer vacuum, gravity, and liquids cycles validated per AAMI-ST8 standard.
- Compliance to AAMI ST8-1994. This standard establishes the minimum construction hospital sterilizers that use saturated steam as the sterilizing agent. The PRIMUS PSS series sterilizers meet or exceed this standard in design and construction.

Safety

The PRIMUS PSS series sterilizers are constructed and tested to meet or exceed the requirements of various national safety codes and standards. The PSS series sterilizers comply with the following requirements:

- Underwriters Laboratory (UL) Electromedical Code 544 as certified by the ETL Testing Labs, Inc.
- Canadian Standards Association CAN/CSA C22.2 NO. 601.1 as certified by the ETL Testing Labs, Inc.
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels.
- California Seismic Pre-Approval.
- National Fire Protection Association Standard 99.

The technology designed into the PRIMUS PSS series sterilizers provides for fail safe controls that give appropriate warnings and signals when required conditions have not been met or malfunctions occur.

To assure of proper operation and sterilization, all items to be processed must be properly cleaned and the manufacturer's instructions must be followed. The sterilizer must be maintained according to the instructions found in the maintenance section of the manual and each type of load must be validated following the applicable standard.

Operator Information

PRIMUS provides information in the Operators Manual that is intended to ensure safe and effective use of the sterilizer. Furthermore, it is recommended that any end user

consult any applicable AAMI standards to assure safe and effective use of the sterilizer for its intended purpose.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1999

Mr. R. Jeff Reed
Engineering Manager
Primus Sterilizer Co., Inc.
117 South 25th Street
Omaha, Nebraska 68131

Re: K991575
Trade Name: PRIMUS Steam Sterilizers
Regulatory Class: II
Product Code: FLE
Dated: November 24, 1999
Received: November 26, 1999

Dear Mr. Reed:

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

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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

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Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: PRIMUS Sterilizer Co., Inc.

510(k) Number: Not known at this time of application

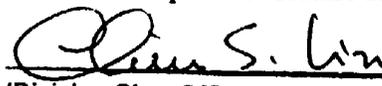
Device Name: PRIMUS Steam Sterilizers

Indications For Use:

The PRIMUS PSS Series Steam Sterilizers are designed for use in Hospital operating suites, central sterile supply and clinical laboratories. The PRIMUS PSS Series Sterilizes provide efficient steam sterilization of non-porous and porous, heat and moisture stabile materials. The PSS Series Sterilizers are available in the following configurations:

13" x 13" x 23" Multi-Functional Sterilizer	Single Door
13" x 13" x 23" Laboratory/Lo	Single Door
16" x 16" x 26" Multi-Functional Sterilizer	Single or Double Door
16" x 16" x 26" Laboratory/Lo	Single or Double Door
20" x 20" x 38" Multi-Functional Sterilizer	Single or Double Door
20" x 20" x 38" Laboratory/Lo	Single or Double Door
26" x 26" x 39" Multi-Functional Sterilizer	Single or Double Door
26" x 26" x 39" Laboratory/Lo	Single or Double Door
26" x 26" x 49" Multi-Functional Sterilizer	Single or Double Door
26" x 26" x 49" Laboratory/Lo	Single or Double Door
26" x 26" x 67" Multi-Functional Sterilizer	Single or Double Door
26" x 26" x 67" Laboratory/Lo	Single or Double Door
26" x 36" x 39" Multi-Functional Sterilizer	Single or Double Door
26" x 36" x 39" Laboratory/Lo	Single or Double Door
26" x 36" x 48" Multi-Functional Sterilizer	Single or Double Door
26" x 36" x 48" Laboratory/Lo	Single or Double Door
26" x 36" x 60" Multi-Functional Sterilizer	Single or Double Door
26" x 36" x 60" Laboratory/Lo	Single or Double Door
26" x 63" x 48" Multi-Functional Sterilizer	Single or Double Door
26" x 63" x 48" Laboratory/Lo	Single or Double Door
26" x 63" x 76" Multi-Functional Sterilizer	Single or Double Door
26" x 63" x 76" Laboratory/Lo	Single or Double Door

Sterilizers are available in Multifunctional models which includes vacuum and gravity cycles and Laboratory/Lo-Temperature models which includes the vacuum and gravity cycles as well as a low temperature feature for pasteurization and inspissation processes.


 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
 510(k) Number 17091575

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