OCT 8 1998

CROSS-CHECKS EO Gas Sterilization Integrator
510(k) Premarket Notification K982547
SteriTec Products Mfg. Co., Inc.

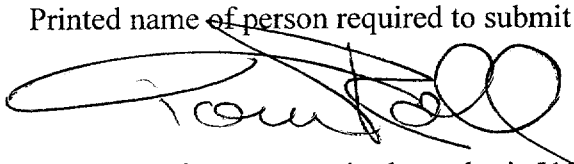
510(k) PREMARKET NOTIFICATION SUMMARY

K982547

SUBMITTER:
STERITEC PRODUCTS MFG. CO., INC.
680 Atchison Way - Suite 600
Castle Rock, CO. 80104
(303) 660-4201
(303) 660-4213 Fax

Establishment Registration Number: 2028456
Date Summary was Prepared November 19, 1996
Date of First Revison February 7, 1997
Date of Second Revision November 5, 1997
Date of Third Revision July 15, 1998

TOM ROLL
Printed name ~~of~~ person required to submit 510(k)



Signature of person required to submit 510(k)

PRESIDENT
Title of person submitting 510(k)

Proprietary Name: SteriTec CROSS-CHECKS EO Gas Sterilization Integrator

Common/ Usual Name: Ethylene Oxide Gas Sterilization Process Integrator

Classification Name: Sterilization Chemical Integrator

Classification: FDA has classified Physical/Chemical Indicators in Class II under Classification Number 80JOJ, Regulation 880.2800

510(k) Summary - continued

Identification of Predicate device:

The SteriTec CROSS-CHECKS EO Gas Sterilization Integrator is a chemical integrator equivalent in construction and performance to the predicate device. Since it is equivalent in construction and performance to the SURGICOT 2 EO Gas Indicator Strip, (FDA 510(k) # K800029 and K800029A) manufactured by SURGICOT of Research Triangle Park, North Carolina (Predicate device), it will perform in the same safe and effective manner as the predicate device as demonstrated in performance tests.

Description of 510(k) submission device:

Intended Use:

The Steritec Cross-Checks EO Integrators are designed to provide an integrated response to EO gas sterilization in hospital sterilizers.Color change occurs between 30 and 45 minutes exposure to EO gas mixture of 88/12 with gas concentration of 600 mg/L, temperature at 130 F and Relative Humidity at 45%.

Comparison to Predicate Device:

Compared to the predicate device our performance data shows the Cross-Checks EO to be substantially equivalent.

Performance Testing:

The SteriTec CROSS-CHECKS EO Gas Sterilization Integrator performance was determined in parallel tests against several biological indicators, (EZTEST, ATTEST, and STS Spore Strips) and in a separate test against the predicate device as well as the Sterigage EO Integrator. The Cross-Checks EO Integrators surpassed the performance of the biologicals for each of the four parameters used in the ethylene oxide sterilization process. In addition, the Cross-Checks EO Integrators surpassed the performance of the Surgicot 2 EO Integrator (the predicate) as well as the Sterigage EO indicator when tested on a side by side basis by an independent laboratory. In both tests , each parameter for EO gas sterilzation was varied while holding the balance of parameters constant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 1998

Mr. Tom Roll
President
SteriTec Products Mfg., Co., Incorporated
680 Atchison Way - Suite 600
Castle Rock, Colorado 80104

Re: K982547
Trade Name: SteriTec CROSS-CHECKS EO Gas Sterilization Integrator
Regulatory Class: II
Product Code: JOJ
Dated: July 16, 1998
Received: July 21, 1998

Dear Mr. Roll:

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): K982547

Device Name: Cross-Checks EO Integrator

Indications For Use:

Steritec Cross-Checks EO Integrators are designed to provide an integrated response to EO gas sterilization in hospital sterilizers. Color change to brown is complete between 30 and 45 minutes exposure to EO gas mixture of 88/12 with gas concentration of 600 mg/L, temperature at 130 F and Relative Humidity at 45%.

(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 X
Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982547