K981497

OCT 29 1998

510(k) SUMMARY

SUBMITTER:

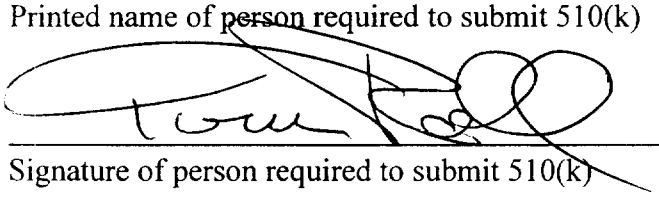
STERITEC PRODUCTS MFG. CO., INC.
680 Atchison Way - Suite 600
Castle Rock, CO. 80104
(303) 660-4201
(303) 660-4213 Fax

Establishment Registration Number: 2028456

Date Summary was Prepared April 23, 1998

Date Summary was Revised August 3, 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 Disposable Biological Test Pack for EO Gas

Common/ Usual Name: Biological Test Pack

Classification Name: Biological

Classification:

The Steritec Disposable Biological Test pack for EO Gas is a disposable biological test pack for testing ethylene oxide gas sterilizers. It falls under the FDA classification of Indicator, Biological Sterilization Process in Class II under Classification Number 80FRC, Regulation 880.2800.

K981497

510(k) Summary - continued

Identification of Predicate device:

The predicate device is the ATI Disposable Biological Test Pack for Ethylene Oxide, (510(k) # 895704) manufactured and distributed by ATI-PyMaH now owned by 3M Corporation.

Description of 510(k) submission device:

Product Description:
SteriTec Disposable Biological Test Packs for EO Gas consist of a self-contained biological indicator containing B. Subtillis spores, placed inside a plastic canister and is covered with a closure cap containing a 5-100 micron porous plastic filter. This assembly is placed into a paper/plastic peel pouch along with a printed record card containing a chemical indicator.

Intended use:
The intended use of this product is for biological testing of EO Gas sterilizers. The performance specification is 130 F, 45% to 60% Relative Humidity, 600 mg/L EO Gas with all survivors at 15 minutes and all killed at 60 minutes.

Comparison to Predicate Device:
The SteriTec Biological Test Pack for EO Gas and the above named predicate device have the same intended use. Both products are test packs containing a self-contained biological. The predicate device uses the Attest biological made by 3M whereas the SteriTec Test Pack uses the EZTest biological made by SGM Biotech. Both products are offered in a paper/plastic pouch. Both products offer resistance to EO gas through their design....the ATI pack uses a plastic syringe opened on one end to house the biological, the SteriTec Pack uses a plastic canister closed at one end completely and held at the other end by a stopper which contains a porous plastic plug. Both Test Packs are meant to extend the time it takes to kill B. Subtillis spores placed in a Ethylene oxide sterilization process.

Performance Testing:
The performance tests showed that at 15 minutes exposure to EO Gas at 600 mg/L with Relative Humidity at 50% and temperature at 130 F, all test packs had 100% survivors. At 25 minutes exposure, the ATI Test Packs had 86% survivors while the SteriTec Test Packs had 100% survivors. At 35 minutes exposure, the ATI Test Packs had 46% survivors while the SteriTec Test Packs had 96% survivors. At 45 minutes exposure the ATI Test packs had 0% survivors while the SteriTec test pack had 12% survivors. Based on these test results conducted at NAMSA Laboratories, The SteriTec Disposable Biological Test Pack for EO gas is substantially equivalent to the ATI Disposable Biological Test Pack for Ethylene Oxide, (FDA 510(k) 895704).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

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

Re: K981497
Trade Name: SteriTec Disposable Biological Test Pack-EO Gas
Regulatory Class: II
Product Code: FRC
Dated: August 3, 1998
Received: August 5, 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): K981497

Device Name: SteriTec Disposable Biological Test Pack for Ethylene Oxide Sterilzation

Indications For Use:

The Steritec Disposable EO Biological Test Pack is designed specifically for biological testing of EO gas sterilizers. The performance specifications for this product are 130 F, 45% to 60% Relative Humidity, 600 mg/L EO gas with all survivors at 15 minutes and all killed at 60 minutes.

(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 K981497