

K965212

510(k) SUMMARY

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FDA/CDRH/ODE/DMC

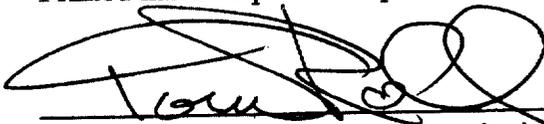
SUBMITTER:

- **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 Revised_ April 14, 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 Chemical Integrator Challenge Pack-Steam

Common/Usual Name: Chemical Integrator Pack for Steam Sterilizers

Classification Name: Chemical Integrator Pack

Classification: ***"Indicator, Chemical Integrator Sterilization Process"*** in Class II under Classification Number 80JOJ, Regulation Number 880.2800.

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510(k) Summary - continued

Identification of Predicate device:

The predicate device is ATI Disposable Test Pack for Steam K952408

Description of 510(k) submission device:

The SteriTec Chemical Integrator Challenge Pack-Steam is designed specifically for load testing of steam sterilizers. The SteriTec Chemical Integrator Challenge Pack-Steam consists of a chemical integrator test sheet placed inside a package of porous and non porous material. This pack provides resistance to the penetration of steam during the sterilization cycle.

Intended use:

The SteriTec Chemical Integrator Challenge Pack-Steam is designed specifically for the testing of 132 °C. (270 °F) pre-vacuum steam sterilizers. The SteriTec Chemical Integrator Challenge Pack-Steam is used to supplement testing with biological packs. It gives the operator assurance of sterilizer performance between biological tests or while waiting for biological test results during the incubation period.

Performance Testing:

The laboratory test data showed that the performance of the Steritec Chemical Integrator Challenge Pack-Steam is equivalent to the predicate. In addition, laboratory test data show that the chemical integrator sheet inside the test pack did not change color completely when the SteriTec Chemical Integrator Challenge Pack-Steam was exposed for 1, 2, and 3 minutes at 132 °C. but did change color completely (PASS) between 3 and 4 minutes. At 130 °C. it did not change when exposed for 1, 2, 3, or 4 minutes but did change between 4 and 5 minutes. At 128 °C. it did not change when exposed for 1, 2, 3, 4, and 5 minutes but did change between 5 and 6 minutes.

Conclusion:

Results of performance testing indicate that the SteriTec Chemical Integrator Challenge Pack-Steam, provides a sufficient load challenge to monitor steam sterilization cycles at 132 °C for 3 minutes or longer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 1998

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

Re: K965212
Trade Name: SteriTec Chemical Integrator Challenge Pack-
Steam
Regulatory Class: II
Product Code: JOJ
Dated: January 28, 1998
Received: January 29, 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.

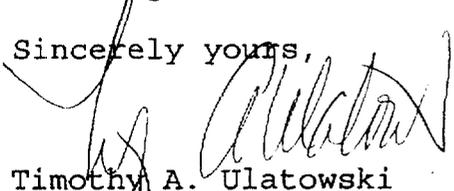
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

