

K 972300

**CROSS-CHECKS P**  
**510(k) Premarket Notification**  
**SteriTec Products Mfg. Co., Inc.**

**MAR 25 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 of Original Submission June 20, 1997  
Date Additional Information provided December 17, 1997  
Date Additional information submitted March, 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 P process indicator strips

Common/Usual Name: Sterrad sterilizer process indicator strips

Classification Name: Process Chemical Indicator

### **Classification:**

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

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## 510(k) Summary - continued

### Identification of Predicate device:

The Steritec Cross-Checks P Process Indicator Strips are similar in design, and function to the:

Johnson & Johnson  
Sterrad Chemical Indicator Strips  
Ref 14100  
510(k) K921910

### Description of Steritec Cross-Checks P process indicator strips:

SteriTec Cross-Checks P strips are 4" x 5/8" process indicators with indicator ink printed onto Tyvek plastic.

### Intended use:

Cross-Checks P chemical process indicator strips are designed to be used in the Sterrad Sterilizer. Cross-Checks P Process Indicator Strips will exhibit a blue to red color change when exposed to hydrogen peroxide during the diffusion phase of the Sterrad cycle. When used as directed, the Cross Checks P strips give visible confirmation that the item has been exposed to hydrogen peroxide during the Sterrad Cycle.

### Comparison to Predicate devices:

Tests substantiated that the Steritec Cross Checks P Indicators performed effectively as described and is equivalent to the claims of the predicate device. Specifically, 200 strips were run in a Sterrad cycle for each of four different exposure timings...10 minutes, 15 minutes, 25 minutes and 30 minutes. The indicator completed its color change between 25 and 30 minutes of diffusion phase exposure.

### EXPOSURE TIME

### RESULTS

10 MINUTES	200/200 INCOMPLETE COLOR CHANGE
15 MINUTES	200/200 INCOMPLETE COLOR CHANGE
25 MINUTES	200/200 POSSIBLE PASS
30 MINUTES	200/200 COMPLETE COLOR CHANGE



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

MAR 25 1998

Re: K972300  
Trade Name: Cross-Checks P  
Regulatory Class: II  
Product Code: JOJ  
Dated: December 19, 1997  
Received: December 29, 1997

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

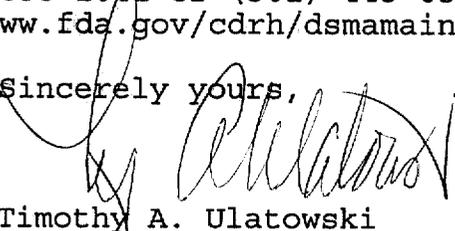
Page 2 - Mr. Roll

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): \_\_\_\_\_

Device Name: SteriTec CROSS CHECKS P Chemical Process Indicators

**Indications For Use:**

**Cross-Checks P** chemical process indicator strips are designed to be used in the Sterrad sterilizer. **Cross-Checks P** Process Indicator Strips will exhibit a blue to red color change when exposed to hydrogen peroxide during the diffusion phase of the Sterrad cycle. When used as directed, the **Cross-Checks P** strips give visible confirmation that the item has been exposed to hydrogen peroxide during the Sterrad cycle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

[Signature]  
Concurrent of CDRE, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K972300

Prescription Use \_\_\_\_\_

OR

Over The-Counter

Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(Optional Format 1 2 96)