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AUG 19 1996

**SteriTec Products Mfg. Co., Inc.
CROSS-CHECKS Steam Sterilization Indicator Strip
FDA 510(k) Application**

510(k) SUMMARY

510(k) PREMARKET NOTIFICATION **SUMMARY**

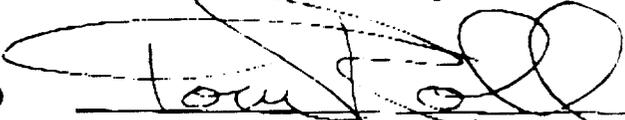
SUBMITTER:

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

- Establishment Registration Number: 2028456

- Date AUGUST 12, 1996

- 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: CROSS-CHECKS Steam Sterilization Indicator Strip

Common/Usual Name: Steam Sterilization Indicator

Classification Name: Physical/Chemical Sterilization Indicator

Classification: Class II

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*510(k) SUMMARY***Identification of Predicate devices:**

The SteriTec product is similar in design, composition and function to the:

- ATI Division of PyMab Corporation Sterilometer Steam Strip® chemical indicator strip for steam

The predicate product was marketed prior to May 28, 1976.

Description of 510(k) submission device.**Intended use:**

SteriTec CROSS-CHECKS sterilization chemical monitoring strips are designed to be utilized in steam sterilizers operating at 132°C to 135° (270°F to 276°F). When used as directed, the SteriTec Cross-Checks indicator strips give visible indication that sterilizing conditions were met. During steam sterilization, the check mark at the end of the strip changes from white to black, becoming as dark or darker in intensity than the black reference arrow printed on the strip.

Comparison to Predicate device:

The basic formula and concept of black to white chemical steam sterilization indicators has not changed dramatically since they were invented in 1932.

Laboratory testing

Laboratory tests were performed to substantiate and verify that the performance of the submitted SteriTec product performed as described. These tests were performed by an independent testing laboratory.

The following tests were performed.**Test 1 - Completed Sterilization Cycle**

3 Minutes @ 132°C (270°F)

ATI and SteriTec sterilization indicator strips were placed in the center of a steam bicr vessel along with a spore strip and sterilized at 132°C (270°F) for three minutes.

Results: All indicator strips changed color to black, indicating proper functioning of the strips. The test spore strips from each run and the control spore strip were tested. All of the test spore strips showed a

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complete kill while the control strip showed all survivors. All indicator strips passed this test.

Test 2 - Incomplete Sterilization Cycle

20 Seconds @ 132°C (270°F)

ATI and SteriTec sterilization indicator strips were placed in the center of a steam bier vessel along with a spore strip and sterilized at 132°C (270°F) for only 20 seconds, to simulate improper sterilization conditions.

Results: All indicator strips showed incomplete color change (none turned to black), indicating improper sterilization conditions and proper functioning of the strips. The test spore strips for each run and the control spore strip were tested. All of the test spore strips and the control strip showed all survivors. All indicator strips passed this test.

Test 3 - Performance Data for Storage of Cross-Check Strips**A. Cross-Checks Strips stored under normal conditions**

SteriTec CROSS-CHECKS sterilization indicator strips were stored for three (3) years and five (5) months at normal room temperatures 10°-38°C (50-100°F) and humidity

Results: The strips were examined for correct indicator color (white). All strips appeared unchanged by the storage process.

B. Cross-Checks Strips stored under normal conditions then sterilized.

SteriTec CROSS-CHECKS sterilization indicator strips were stored for three (3) years and five (5) months at normal room temperatures 10°-38°C (50-100°F) and humidity. The indicator strips were placed in the center of a gravity steam sterilizer and sterilized at 121°C (250°F) for fifteen minutes.

Results: All indicator strips changed color to black, indicating proper functioning of the strips and no change in their performance caused by normal storage.

C. Cross-Checks Strips subjected to extreme temperature.

SteriTec CROSS-CHECKS sterilization indicator strips were stored in a constant temperature chamber at 57° C. (134° F.) for eight (8) days. The temperature of 57° C. (134° F.) was selected since it would represent a higher temperature than any storage area in institutions where the strips would be stored.

Results: Following storage the strips were removed and examined. The color of the strip had NOT changed from its original normal white color.

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- D. Cross-Checks Strips subjected to extreme temperature then sterilized. Cross-Check strips were stored in a constant temperature chamber at 57° C. (134° F.) for eight (8) days. Strips were placed in the center of a gravity steam sterilizer and sterilized at 121° C (250° F) for fifteen minutes.
Results: Following the fifteen minute sterilization cycle, all test strips were removed and evaluated. All indicator strips changed color to black, indicating proper functioning of the strips and no change in their performance caused by storage in extreme heat conditions.
- E. Cross-Checks Strips subjected to extreme humidity. SteriTec CROSS-CHECKS sterilization indicator strips were stored in a vacuum desiccator (bell jar) along a saturated sodium chloride solution with the humidity controlled at 75%. The bell jar was then stored in a constant temperature chamber at normal room temperature of 20° C. (68° F.) for seven (7) days.
Results: Following storage the strips were removed and examined. The color of the strip had NOT changed from its original normal white color.
- F. Cross-Checks Strips subjected to extreme humidity then sterilized. SteriTec CROSS-CHECKS sterilization indicator strips were stored in a vacuum desiccator (bell jar) along a saturated sodium chloride solution with the humidity controlled at 75%. The bell jar was then stored in a constant temperature chamber at normal room temperature of 20° C. (68° F.) for seven (7) days. The indicator strips were placed in the center of a gravity steam sterilizer and sterilized at 121° C (250° F) for fifteen minutes.
Results: Following the fifteen minute sterilization cycle, all test strips were removed and evaluated. All indicator strips changed color to black, indicating proper functioning of the strips and no change in their performance caused by storage in extreme humidity conditions.
- G. Cross-Checks Strips subjected to extreme temperature and humidity. SteriTec Cross-Check sterilization indicator strips were stored in a vacuum desiccator (bell jar) along a saturated sodium chloride solution with the humidity controlled at 75%. The bell jar was then placed in a constant temperature chamber at 57° C. (134° F.) for eight (8) days. The temperature of 57° C. (134° F.) was selected since it would represent a higher temperature than any storage area in institutions where the strips would be stored.
Results: Following storage the strips were removed and examined. The

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- color of the strip had changed from its original white color to a light tan.
- H. Cross-Checks Strips subjected to extreme temperature and humidity then sterilized.

SteriTec Cross-Check sterilization indicator strips were stored in a vacuum desiccator (bell jar) along a saturated sodium chloride solution with the humidity controlled at 75%. The bell jar was then placed in a constant temperature chamber at 57° C. (134° F.) for eight (8) days

Results: Following the fifteen minute sterilization cycle, the test strips were removed and evaluated. All indicator strips changed color to black, indicating proper functioning of the strips and no change in their performance caused by storage in extreme heat and humidity conditions.

Test 4 - Performance Data for Cross-Checks Strips sterilized at various sterilization temperatures and sterilization times.

- (1) SteriTec Cross-Checks sterilization indicator strips catalog numbers CI 102 and CI 111 were subjected to a steam sterilization cycles for 3 minutes at the following sterilization temperatures:
124°C 128°C 130°C 132°C 134°C
 Approximately 300 strips along with 12 biological spore strips were run at each temperature range.
- (2) SteriTec sterilization indicator strips catalog numbers CI 102 and CI 111 were subjected to a steam sterilization cycles at 132°C for the following times:
1 min 2 min 2½ min 3 min 3½ min
 Approximately 300 strips along with 12 biological spore strips were run at each temperature range.

Interpretation of Results:

To make the interpretation as objective as possible a panel of three people selected by the independent laboratory were used to make the PASS/FAIL determinations. These results are shown in Tables 1 and 2. Since a few of the results from the first set of interpreters were considered outside the product specifications another set of three interpreters were hired by SteriTec to again make the interpretations of the same indicators described in (1) and (2) above. These interpreters were all nurses who generally have more experience in chemical indicator interpretations. These results are shown in Tables 3 and 4.

Conclusion:

Results of performance testing of the SteriTec Cross-Checks Indicator Strips indicate that the submitted product, SteriTec Cross-Checks, performed as

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specified and in all cases completed a color change only after the biological spore strips tested at the same time under the same conditions, had expired. The interpretations of the second set of interpreters (Nurses) were more uniform in their determinations of whether or not the indicators passed or failed.

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TABLE 1

Additional Performance Testing - Cross-Checks CI 102														
3 Minutes Sterilization Time at:														
124°C			128°C			130°C			132°C			134°C		
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-
0	275	12/12	0	300	1/12	108	183	0/12	342	92	0/12	292	0	0/12
132°C for:														
1 minute			2 minutes			2 1/2 minutes			3 minutes			3 1/2 minutes		
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-
0	292	9/12	17	275	0/12	142	150	0/12	342	92	0/12	292	0	0/12

TABLE 1

Notes: Pos=Positive result (PASS)
 Neg=Negative result (FAIL)
 Bio=Biological spore strips. + = Survivors - = No Survivors

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TABLE 2

Additional Performance Testing - Cross-Checks CI 111														
3 Minutes Sterilization Time at:														
124°C			128°C			130°C			132°C			134°C		
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-
0	300	12/12	0	292	1/12	75	225	0/12	233	217	0/12	292	0	0/12
137°C for:														
1 minute			2 minutes			2½ minutes			3 minutes			3½ minutes		
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-
0	300	9/12	0	283	0/12	108	192	0/12	233	217	0/12	300	0	0/12

TABLE 2

Notes: Pos=Positive result (PASS)

Neg=Negative result (FAIL)

Bio=Biological spore strips. + = Survivors - = No Survivors

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TABLE 3

Additional Performance Testing - Cross-Checks CI 102 (Nurse Interpreters)														
3 Minutes Sterilization Time at:														
124°C			128°C			130°C			132°C			134°C		
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-
0	275	12/12	0	300	1/12	92	200	0/12	400	50	0/12	300	0	0/12
132°C for:														
1 minute			2 minutes			2½ minutes			3 minutes			3½ minutes		
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-
0	300	9/12	0	300	0/12	133	167	0/12	400	50	0/12	300	0	0/12

TABLE 3

Notes: Pos=Positive result (PASS)
Neg=Negative result (FAIL)

Bio=Biological spore strips.
+ = Survivors
- = No Survivors

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TABLE 4

Additional Performance Testing - Cross-Checks CI 111 (Nurse Interpreters)														
3 Minutes Sterilization Time at:														
124°C		128°C		130°C		132°C		134°C						
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-			
0	275	12/12	0	292	1/12	50	250	0/12	458	8	0/12	300	0	0/12
132°C for:														
1 minute		2 minutes		2 1/2 minutes		3 minutes		3 1/2 minutes						
Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-	Pos	Neg	Bio +/-			
0	275	9/12	0	283	0/12	142	150	0/12	458	8	0/12	292	0	0/12

TABLE 4

Notes: Pos=Positive result (PASS)

Neg=Negative result (FAIL)

Bio=Biological spore strips.

+ = Survivors

- = No Survivors