

K961721

3 pages

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Steritec Products Mfg. Co., Inc.
Steritec Disposable Biological Test Pack
FDA 510(k) Application

Page 30

510(k) SUMMARY

SUBMITTER:

- **STERITEC PRODUCTS MFG. CO., INC.**
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- Establishment Registration Number: 2028456
- Date Summary was Prepared August 20, 1996 (Revised)
- TOM ROLL
Printed name of person required to submit 510(k)
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Signature of person required to submit 510(k)
- PRESIDENT
Title of person submitting 510(k)

Proprietary Name: SteriTec Disposable Biological Test Pack

Common/Usual Name: Biological Test Pack

Classification Name: Biological

Classification: The SteriTec Disposable Biological Test Pack is a disposable biological test pack for testing steam sterilizers. It falls under the FDA classification of **Indicator, Biological Sterilization Process** in Class II under Classification Number 80FRC, Regulation Number 880.2800.

Steritec Products Mfg. Co., Inc.
Steritec Disposable Biological Test Pack
FDA 510(k) Application

Page 31

510(k) Summary - continued

Identification of Predicate device:

The SteriTec disposable biological test pack is equivalent in function and operation to the standard AAMI biological test pack which consists of 16 surgical towels measuring 16" x 26" which when folded according to AAMI directions form a 9" x 9" x 6" test pack. A biological indicator is placed in the middle of the AAMI pack which is considered the "Standard" for conducting a biological test in steam sterilizers. The AAMI standard test pack is the predicate device used in this submission.

Description of 510(k) submission device:

Intended use:

The *SteriTec Disposable Biological Test Pack* is a steam sterilization monitor designed specifically for biological testing of 121°C (250°F) gravity or 132°C (270°F) pre-vacuum steam sterilizers. The pack consists of a self-contained biological indicator containing *B. stearothermophilus* spores inside a small package of porous and nonporous materials.

Comparison to Predicate devices:

Laboratory testing

Laboratory tests were performed to substantiate and verify that the performance of the submitted SteriTec product performed as described and is equivalent in function to the predicate device.

Two series of tests were performed to show that the SteriTec Disposable Biological Test Pack performed equivalently to the standard AAMI Biological Challenge Test packs.

Series 1

Gravity Sterilizer 121 °C

Sterilization runs were also conducted in a typical hospital gravity sterilizer. The sterilizer used was a AMSCO[®], Model 57CR, Type QDS-1624 gravity steam sterilizer. Tests were conducted at 10 minutes, 12 minutes, 15 minutes and 20 minutes exposures.

Steritec Products Mfg. Co., Inc.
Steritec Disposable Biological Test Pack
FDA 510(k) Application

Page 32

Series 2

Prevacuum sterilizer at 132 C

Sterilization runs were also conducted in a pre-vacuum sterilizer run at 132 C (270 F). The sterilizer used for this series was a specially constructed laboratory prevacuum steam sterilizer built around an Amsco 20" x 20" x 40" chamber. All runs were done using a typical Amsco Eagle Series cycle consisting of a one minute purge and four prevacuum pulses. Tests were run at one (1) minute, two (2) minutes and three (3) minutes at 132 C.

Results

Gravity Sterilizer 121 °C

After 10 minutes exposure, all the biologicals survived both in the AAMI standard pack and the Steritec Disposable Biological test packs. After 12 minutes exposure, both packs experienced partial survivors. After 15 minutes and 20 minutes exposures, all the biologicals were killed in both the AAMI and Steritec test packs.

Prevacuum Sterilizer 132 C

After 1 minute and 2 minute exposures, both packs experienced partial survivors. After 3 minute exposure, all the biologicals were killed in both the AAMI and Steritec test packs.

Conclusion:

The results of this testing show that the SteriTec Disposable Biological Test Packs paralleled the results of the AAMI standard cloth biological test pack.