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SteriTec Products Mfg. Co., Inc.
CROSS-CHECKS EO Chemical Process Indicator
FDA 510(k) Application
May 27, 1996
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K 952244

510(k) SUMMARY

SUBMITTER:

- **STERITEC PRODUCTS MFG. CO., INC.**
680 Atchison Way - Suite 600
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(303) 660-4201
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- Establishment Registration Number: 2028456

- Date Summary Summary was Prepared May 27, 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 EO

Common/Usual Name: EO Process Indicator

Classification Name: Process 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 EO gas process indicator strip product is similar in design, composition and function to the:

Surgicot 2[®] EO Gas Indicator, chemical indicator strip, which was marketed prior to May 28, 1976.

Description of 510(k) submission device:

Product Description:

SteriTec CROSS-CHECKS EO process indicators are a pale yellow to brown chemical indicator strip that changes color during ethylene oxide processing.

Intended use:

SteriTec CROSS-CHECKS EO gas process indicator monitoring strips are a yellow to brown chemical indicator strip that changes color during Ethylene Oxide (EO) processing. They indicate that the item has been processed in Ethylene Oxide.

Comparison to Predicate devices:

The basic formula and concept of chemical Ethylene Oxide process indicators has not changed dramatically since they were invented in the fifties and sixties.

Laboratory testing

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

Conclusion:

Results of performance testing indicate that the submitted product, SteriTec CROSS CHECKS EO, performed in a safe and effective manner equivalently to the Surgicot 2[®] predicate device.