

K960441

SteriTec Products Mfg. Co., Inc.  
Steritec Integrgraph Integrators  
FDA 510(k) Application-K960441  
Original Submission-January 24, 1996  
Current Date-May 2, 1997

510(k) SUMMARY

MAY - 8 1997

# **510(k) PREMARKET NOTIFICATION** **SUMMARY**

## **510(k) Premarket Notification Summary**

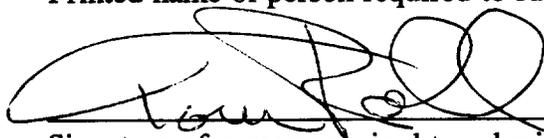
### **SUBMITTER:**

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

- Establishment Registration Number: 2028456

- Date May 2, 1997

- 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: *Integrgraph*

Common/Usual Name: Steam Sterilization Indicator/Integrator

Classification Name: Sterilization Indicator

Classification:

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

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**Identification of Predicate devices:**

The Steritec *Integrator* CI 101 is a chemical indicator/integrator equivalent in construction and operation to the ATI Steam Clox (predicate device). Since the Steritec *Integrator* is equivalent in construction to the predicate device, it will perform equivalently.

**Description of 510(k) submission device:**

**Intended use:**

The Steritec *Integrator* is designed to provide an integrated response to steam sterilization at 132 C for sterilizers operating for 3 ½ minutes or longer.

**Comparison to Predicate device:**

Compared to the predicate device our performance data shows the *Integrator* Integrator to be substantially equivalent

**Performance Testing:**

To demonstrate the performance of the SteriTec *Integrator* the product was tested:

- (1) At multiple sterilization temperatures and times against biological indicators.
- (2) For stability after storage in high temperature conditions.
- (3) For stability after storage in high humidity conditions.
- (4) For stability after storage for two and one half years years.
- (5) For stability after being sterilized and then stored for two years.

**No false "PASS" Indications**

In all cases they indicated properly whether the sterilization conditions had been met or not in the sterilizer chamber as verified by biological spore strips. There were NO instances in which the SteriTec strips indicated that sterilization conditions were met when they were not (NO FALSE PASS RESULTS).

**Margin of Safety**

Test results show the SteriTec strips provide a "margin of safety". During these tests, No SteriTec strip tested provided a "PASS" test result in tests when there were any biological spore survivors.

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**Stability Testing:**

Independent laboratory testing showed the SteriTec *Integrgraph* is stable after being subjected to extremes of heat and high humidity. In addition, under room temperature storage of both exposed and unexposed strips for 2 years the strips also performed satisfactorily. All strips maintained their purple color after storage testing. After exposure to sterilization conditions, the indicators properly changed color from purple to green.