

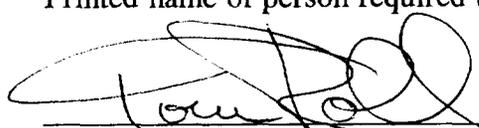
APR - 2 1997

K953122

SteriTec Products Mfg. Co., Inc.
SteriTec Dry Heat Indicator Label

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
- Original Date Summary was Prepared May 15, 1995
Date of this submission February 12, 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: SteriTec Dry Heat Indicator Label
Common/Usual Name: Dry Heat Sterilization 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.

SteriTec Products Mfg. Co., Inc.
SteriTec Dry Heat Indicator Label

510(k) Summary - continued

Identification of Predicate device:

The SteriTec Dry Heat Indicator Label is a sterilization process indicator label product and is similar in design, composition and function to the:

ATI Dry Heat Indicator Labels
ATI Division of PyMah Corporation
89 Rt. 206, P.O. Box 1114
Somerville, NJ 08876
(800) 526-3538 (818) 765-7830

Description of Steritec Dry Heat Indicator Label:

SteriTec Dry Heat Indicator Labels are process indicators that turn color from green to dark brown/black during dry heat processing at 160 C. The labels will usually complete their color change in less than 10 minutes at this temperature.

Intended use:

SteriTec Dry Heat Indicator Labels are designed to be utilized in dry heat (hot air) sterilizers operating at 160 C. The label provides clear identification of processed versus unprocessed items.

Comparison to Predicate devices:

Tests substantiated that the Steritec Dry Heat Indicator Label performed safely and effectively as described and is equivalent to the predicate device.