JUN 10 1999

**510(k) SUMMARY**

K990246

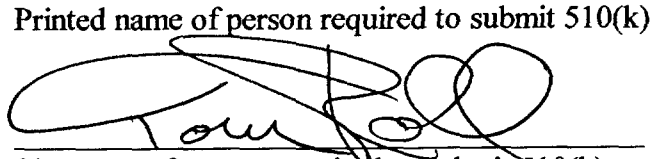
**SUBMITTER:**

**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

Date Summary was Prepared: January 20, 1999

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:** Steri-Pak LF Bowie-Dick Test Pack

**Common/ Usual Name:** Disposable Bowie-Dick Test Pack

**Classification Name:** Physical/Chemical Sterilization Indicator

**Classification:** The Steri-Pak LF Bowie-Dick Test Pack for use in prevacuum steam sterilizers is a disposable "Physical/Chemical sterilization indicators" test pack for the daily monitoring of prevacuum steam sterilizers to detect air leaks, inadequate steam penetration, and vacuum pump failures. It contains no Lead. It falls under the FDA classification of Indicator, Physical/Chemical Sterilization Process in Class II under Regulation Number 880.2800.

**Predicate Device:** SteriTec Steri-Pak Bowie Dick Test Pack 510(k) 982188

**510(k) Summary - continued**

**Description of 510(k) Submission Device:**

***Intended use/Device Description:***

The Steri-Pak LF Bowie-Dick Test Pack is designed specifically for daily monitoring of pre-vacuum steam sterilizers to detect the presence of residual air. The test pack is approximately 3¾" x 5¼" x¾" in size consisting of a stack of 25 layers of porous blotter paper with a plastic laminated layer at the bottom. Embedded within the pack is an indicator sheet with steam sensitive ink printed on it. The indicator sheet changes to black during a typical Bowie-Dick test and will have a lighter, blue color in the center if a significant amount of air is present during the test.

***Comparison to Predicate Device:***
Laboratory tests show the Steri-Pak LF Bowie-Dick Test Pack and the above named predicate device have the same intended use in that they are disposable chemical indicator test packs designed specifically for daily monitoring of pre-vacuum steam sterilizers to detect the presence of residual air.

***Summary of Performance Testing:***
Based on the results of laboratory tests, the Steri-Pak LF Bowie-Dick Test Pack is substantially equivalent to the SteriTec Steri-Pak Bowie Dick Test Pack 510(k) 982188.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1999

Mr. Lon Bruso
Vice President
SteriTec Products Manufacturing Company, Incorporated
680 Atchison Way - Suite 600
Castle Rock, Colorado 80104

Re: K990246
Trade Name: Steri-Pak LF Bowie-Dick Test Pack
Regulatory Class: II
Product Code: JOJ
Dated: March 29, 1999
Received: March 30, 1999

Dear Mr. Bruso:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):**_____

**Device Name:__Steri-Pak LF Bowie Dick Test Pack**_____

**Indications For Use:**

The Steri-Pak LF Bowie Dick Test Pack manufactured by SteriTec Products Mfg. Co., Inc. is designed to detect the presence of residual air in prevacuum steam sterilizers operating at 132 °C. It is designed to be used for daily Bowie Dick testing of hospital sterilizers as described in AAMI/ANSI ST46 section 7.7. It contains no Lead.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K990246

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number