

JUL 12 1999

**510(k) Summary**

K990761

**Submitter:** Tuttnauer USA Co. Ltd.  
33 Comac Loop, Equi-Park  
Ronkonkoma, NY 11779

Phone: 800-624-5836  
Fax: 516-737-0720

**Contact Name:** Robert R. Basile

**Date Prepared:** March 8, 1999

**Common Name:** Sterilizer Cassette

**Trade Name:** Tuttnauer Mini Container Cassette  
Tuttnauer Standard Case Cassette

**Classification Name:** Accessory to Sterilization Wrap  
Class II Device - 21 C.F.R. § 880.6850

**Substantial Equivalence:**

The Tuttnauer Mini Container and Standard Case Cassettes are substantially equivalent to the following currently marketed sterilization cassettes:

<u>Company</u>	<u>Product Name</u>	<u>510(k) Clearance Number</u>
Riley Medical, Inc.	Surgical Instrument Tray	K944025
Plastic Sterilizing Tray Corp.	PST Trays	Unknown
C/T Med-Systems Ltd., Inc	C/T Med-Systems Cassette System	K980065

**General Description:**

The Tuttnauer Mini Container Cassette and Tuttnauer Standard Case Cassette are sterilization cassettes that are designed to allow steam to pass through the device to ensure effective sterilization. The Mini Containers are small to medium-sized trays with silicone mats that are useful in the organization, sterilization and transport of medical and dental instruments. An array of Mini Container sizes are available to accommodate various instrument configurations. The Standard Case Cassette features a slotted instrument holder and are designed to hold hand-held instruments 2.5mm to 8mm in diameter.

**Design and Materials:**

Tuttnauer cassettes are manufactured from a chemical resistant thermoplastic that has been tested by its manufacturer for capability with all forms of sterilization. Cassette inserts used to stabilize the instruments are manufactured from biomedical grade silicone.

**Intended Use:**

The Tuttnauer Mini Container and Standard Case Cassettes are general dental/medical instrument cassettes intended to hold instruments and accessories in place during the sterilization cycle. The devices are indicated for use in steam sterilization.

**Technology Considerations:**

The following is a chart showing the similarities and difference between the Tuttnauer Mini Container and Tuttnauer Standard Case cassettes and their predicate devices:

	<b>Tuttnauer Cassettes</b>	<b>Riley Medical</b>	<b>PST Trays</b>	<b>C/T Medical Systems</b>
Intended Use – To hold instruments during sterilization	Yes	Yes	Yes	Yes
Reusable	Yes	Yes	Yes	Yes
Sterilization by Gravity Steam	Yes	Yes	Yes	Yes
Sterilization by Vacuum Steam	Yes	Yes	Yes	Yes
Sterilization by Ethylene Oxide	Not Requested	Yes	Yes	Yes
Tested to AAMI TIR 12-1994	Yes	No	Unknown	Yes
Half-cycle validation to challenge sterilization	Yes	No	Unknown	Yes
Various size cassettes available	Yes	Yes	Yes	Yes
Various methods for holding instruments	Yes	Yes	Yes	Yes
Latch system to hold lid in place	Yes	Yes	Yes	Yes
Material	Plastic Polymer	Plastic Polymer	Plastic Polymer	Aluminum and Stainless Steel

**Non-Clinical Testing:**

Tuttnauer conducted validation studies on the Mini Container and Standard Case cassettes for gravity and prevacuum steam sterilization. Three half-cycle tests were performed on each cassette for each method of sterilization. Successful sterilization was accomplished with all cassettes in each test.

**Conclusion:**

It is Tuttnauer USA Co. Ltd.'s conclusion that the Tuttnauer Mini Container Cassette and Tuttnauer Standard Case Cassette are substantially equivalent to their predicate devices. Based upon test data submitted, Tuttnauer cassettes allow effective steam sterilization of instruments contained within them during normal autoclave operation.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 12 1999

Tuttnauer USA Company, LTD.  
c/o Mark M. Yacura, Esquire  
Akin, Gump, Strauss, Hauer & Feld, L.L.P.  
1333 New Hampshire Avenue, N.W.  
Suite 400  
Washington, DC 20036

Re: K990761  
Trade Name: Tuttnauer Mini Container Cassette, Tuttnauer  
Standard Case Cassette  
Regulatory Class: II  
Product Code: FRG  
Dated: June 7, 1999  
Received: June 7, 1999

Dear Mark M. Yacura, Esquire:

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 (Pre-market 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.

Page 2 - Mark M. Yacura, Esquire

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,



A

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

Enclosure

Indications for Use Statement

510(k) Number: K990761

Device Name: Tuttnauer Mini Container Cassette  
Tuttnauer Standard Case Cassette

Indications For Use: The Tuttnauer Mini Container and Standard Case Cassettes are general dental/medical instrument cassettes intended to hold instruments and accessories in place during the sterilization cycle. The devices are indicated for use in both gravity and pre-vacuum steam sterilization.

(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  X

(Per 21 C.F.R. § 801.109)

Quin S. Lin

(Optional Format 1-2-96)

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

510(k) Number  K 990761