C/T MED-SYSTEMS LTD., INC.

K980065

MAY 11 1998

Non-Confidential Summary of Safety and Effectiveness

January 6, 1998

C/T Med- Systems Ltd., Inc.
3755 N. Arlington Ave.
Indianapolis, IN 46218

Tel - (317) 543-4250
Fax - (317) 543-4203

Official Contact:	Alan Booker - Operations Manager
Proprietary or Trade Name:	C/T Med-Systems Cassette System
Common/Usual Name:	Sterilization Cassettes
Classification Name:	Sterilization Wrapper Pack, Bag and Accessories
Device:	C/T Med-Systems Cassette system
Predicate Devices:	Sterilization Cassettes - K962545
	Hu-Friedy - IMS - K844002

Device Description:

A cassette system and accessories designed to hold various dental and medical instrument to be cleaned and sterilized. The design is a metal, aluminum and stainless steel container which has various methods of holding the instruments in place. Available in various sizes ranging which have a typical size of 1.5" x 3.5" x 1" to 8" x 15.5" x 2.5".

Indicated Use -- General dental / medical instrument cassettes intended to hold instruments and accessories in place throughout the entire instrument use, cleaning and sterilization cycle. These cassettes are suitable for Gravity Steam, Pulsing High Vacuum steam and EO sterilization. Instruments may be cleaned by chemical sterilant.

Environment of Use -- Hospital, Operating Room (OR), physician and dental office or places where instruments are sterilized.

Summary of Performance testing --

The C/T Med-System Cassette system was independently tested according to AAMI TIR No. 12-1994 for its performance under three (3) sterilization methods - Pulsing High Vacuum and Gravity steam and Ethylene Oxide (EO). It was also tested for ultrasonic cleaning by Indiana University.

Comparison to Predicate Devices:

Attribute	C/T Med-Systems	Sterilization Cassette K962545	Hu-Friedy (IMS) K844002
Use			
Indicated for holding dental and medical instruments and accessories in place throughout entire instrument use, cleaning and sterilization cycle	Yes	Yes	Assumed
Intended to be reused	Yes	Yes	Yes
Sterilization by Gravity Steam, Pulsing High Vacuum Steam and Ethylene oxide	Yes	Autoclave	Not specified
Design			
Various sizes offered ranging typically ranging from 2.5" x 8" x 1.5" to 8" x 15.5" x 2.5"	Yes	Yes	Yes
Utilizes various methods of holding instruments in place	Yes	Yes	Yes
May incorporate latch system to hold lid in place	Yes	Yes	Yes

Performance Standards / Specifications			
Tested in accordance to AAMI TIR No. 12-1994	Yes	No but other method used	Not known
Validation study performed with half cycles to challenge sterilization method used	Yes	No	Not known
AAMI ST 33 -1992 requirements 3.4-3.5 Instructions provided for different cleaning methods of cassette	Yes	Assumed	Assumed
3.6-4.2 Instructions for inspections	Yes	Assumed	Assumed
6.2.2 Sterilization manufacturer documentation available	Yes	Yes	Not known
6.2.3 Drying time in labeling	Yes	Not known	Not known
6.2.4 EO residual removal in labeling	Yes	Not known	Not known
6.3 User (basic) responsibilities listed in labeling	Yes	Not known	Not known
7.3.1 Routine inspection in labeling	Yes	Not known	Not known
Materials			
Aluminum and stainless steel	Yes	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates - Sterilization Cassette - K962545 and Hu-Friedy - IMS - K844002.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 1998

Mr. Alan Booker
Operations Manager
C/t Med Systems, Ltd., Incorporated
3755 North Arlington Avenue
Indianapolis, Indiana 46218

Re: K980065
Trade Name: C/T Med-Systems - Sterilization Cassette System
Regulatory Class: II
Product Code: KCT
Dated: April 22, 1998
Received: April 23, 1998

Dear Mr. Booker:

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

INDICATIONS FOR USE

510(k) Number: ____________ (to be assigned)

Device Name: C/T Med-Systems Instrument Cassette System

Intended Use : General dental / medical instrument cassettes intended to hold instruments and accessories in place throughout the entire instrument use, cleaning and sterilization cycle. These cassettes are suitable for Gravity Steam, Pre-vacuum steam and EO sterilization.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ **or** **Over-the-counter use** __
(Per CFR 801.109)

(Division Sign-Off) George A. Mills for Chiu S. Lin PhD
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number ____________