

NOV 13 1998

K983135

510(k) Summary
CardioThoracic Systems, Inc.
Blower/Mister
510(k) Notification K983135

GENERAL INFORMATION

Manufacturer: CardioThoracic Systems, Inc.
10600 North Tantau Avenue
Cupertino, California
(408) 342-1700
(408) 342-1717 FAX
Est. Reg. No. 9027735

Contact Person: Michael J. Billig
Vice President, Regulatory, Quality, and Clinical
Research

Date Prepared: September 03, 1998

DEVICE DESCRIPTION

Classification: Jet Lavage 21 CFR 880.5475

Trade Name: CTS Blower/Mister

Generic/Common Name: Lavage or irrigation device

PREDICATE DEVICES

ClearView Blower/Mister manufactured by Medtronic
FlexiView CO₂ Blower with Mist manufactured by Ethicon

INTENDED USE

The CTS Blower/Mister is intended to clear an anastomotic site or other surgical sites for improved visibility.

PRODUCT DESCRIPTION

The CTS Blower/Mister is comprised of a handpiece and malleable shaft enabling positioning of the device near the targeted site. Connectors on the device allow for hook-up to standard gas and saline sources. The device permits both an adjustable flow of gas and a mist of saline to be deposited at the targeted site.

SUBSTANTIAL EQUIVALENCE

The CTS Blower/Mister is intended to clear a wound or surgical site for improved visibility. The Blower/Mister is substantially equivalent to Medtronic's ClearView Blower/Mister and Ethicon's FlexiView CO₂ Blower with Mist in regards to intended use, patient population, functionality and performance.

Functional bench testing has been conducted and the results of the testing verified that the Blower/Mister performs as designed and is suitable for its intended use.

SUMMARY

As contained in this 510(k) summary, the CTS Blower/Mister is substantially equivalent to the predicate device identified in that the Blower/Mister has a similar intended use, patient population and performance as the predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael J. Billig
Vice President, Regulatory, Quality, and
Clinical Research
CardioThoracic Systems, Incorporated
10600 North Tantau Avenue
Cupertino, California 95014

Re: K983135
Trade Name: Blower/Mister
Regulatory Class: II
Product Code: FQH
Dated: September 3, 1998
Received: September 8, 1998

Dear Mr. Billig:

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.

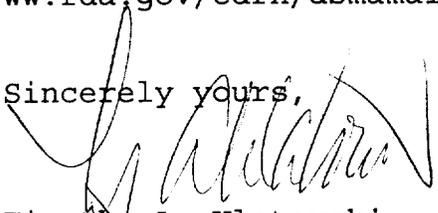
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

K983135

CardioThoracic Systems, Inc.
CTS Blower/Mister
510(k) Premarket Notification

STATEMENT OF INDICATIONS FOR USE

The CTS Blower/Mister is intended to clear an anastomotic site or other surgical sites for improved visibility.

Patricia Cucenite

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K983135