

DEC - 8 1997

Medtronic, Inc.
Medtronic DLP
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Grand Rapids, MI 49501-0409
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510(k) SUMMARY

PROPRIETARY NAME: ClearView Blower/Mister
COMMON NAME: Lavage or irrigation device
CLASSIFICATION NAME: Jet lavage per 21 CFR 880.5475

LEGALLY MARKETED PREDICATE DEVICE

The claim of substantial equivalence of the ClearView Blower/Mister is made to the RMI VisuFlow Surgical Site Visualization Wand, K922083.

DEVICE DESCRIPTION

The ClearView Blower/Mister includes a hand grip with a 3 1/4" or 6 1/2" malleable stainless steel shaft for ease of positioning the device near the surgical site. The soft, silicone tip contains a plastic tube which carries saline to the tip. The proximal end includes a fluid inlet line which terminates in a locking female luer for connection to the fluid administration set. The gas line, located on the proximal end, has an in-line 0.2 micron filter and terminates in a slip connector for connection to the gas source tubing.

INTENDED USE

This device is intended for use during procedures when a wound or surgical site must be cleared by non-contact means for improved visibility at the site.

TECHNOLOGICAL CHARACTERISTICS

Both devices clear the surgical site using a pressurized stream of filtered USP medical air and a saline mist. The gas line in both devices includes a 0.2 micron hydrophobic filter. Both RMI and DLP devices require a 8' PVC gas line and standard IV administration set for delivering air and saline to the device. With both products, the mist is controlled by adjusting the saline using the roller clamp and/or the air using the regulated gas flow control. Both devices are sterile, non-pyrogenic and single use only.

NON-CLINICAL PERFORMANCE DATA

This device was tested to determine the force exerted by the gas/saline stream under various flow rates at varying distances from a flat surface. The force was consistent over the range of discharge heights for a given flow rate. Both models performed consistently over the tested flow and discharge height conditions.

This device and the predicate device were tested to determine the force exerted by the gas/saline stream at the labeled maximum flow rates at the labeled maximum and minimum discharge heights. The predicate device exerted a force approximately 70% greater at maximum flow and minimum discharge height conditions.

The mist pattern delivered by this device and the predicate device were measured under typical air flow rates over the recommended range of saline flow rates and discharge heights. The mist pattern of this device was circular in shape and centered under the discharge tip. The mist pattern of the predicate device is oval in shape with the major axis perpendicular to the discharge tip.

This device was tested to determine the effect that repeated/multiple bends of the malleable shaft have on the performance of the product under fixed flow conditions. No measurable changes in air or saline flow rates were observed.

SUBSTANTIAL EQUIVALENCE CONCLUSION

The performance testing results demonstrate the ClearView Blower/Mister is substantially equivalent to the RMI Surgical Site Visualization Wand.

Gretchen Hartlage
September 12, 1997



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Gretchen Hartlage
Senior Product Regulation Manager
DLP, Division of Medtronic, Incorporated
620 Watson, S.W.
Grands Rapids, Michigan 49501-0409

Re: K973485
Trade Name: ClearView Blower/Mister
Regulatory Class: II
Product Code: FQH
Dated: September 12, 1997
Received: September 15, 1997

Dear Ms. Hartlage:

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.

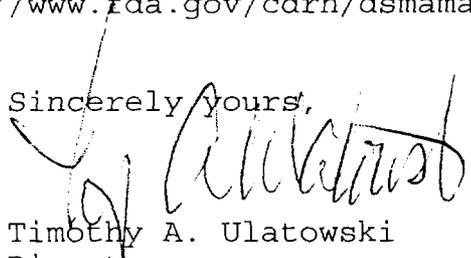
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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/dsmmain.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

K973485

510(k) Number (if known): _____

Device Name: ClearView Blower/Mister

Indications For Use:

This device is intended for use during procedures when a wound or surgical site must be cleared by non-contact means for improved visibility at the site.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Curran
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973485

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____