

11.0 Summary of Safety and Effectiveness**MAR 15 2000**

Submitter Name and Address: MEDevices, Inc.
1840 Industrial Drive, Suite 210
Libertyville, Illinois 60048

Contact Person: Michele H. Vovolka
Telephone Number: 847-856-0355

Date Summary Prepared: October 3, 1999

Proprietary Name: SightSure Operation Indicator

Common Name: Dual Lumen Tube Operation Indicator

Classification Name: Gastrointestinal Tube and Accessories

Device Classification: Class II per 21 CFR 876.5980

Panel Code: 78

Procodes: KNT

Predicate Devices: Nasal Flowmeter
Thrope Tube Flowmeter

Product Design:

The device is characterized by a chamber that is filled with sterile water prior to use. Negative pressure provided by a functioning dual lumen medical tube vent lumen is applied to the chamber through a tube linking the vent (sump) lumen to the sealed chamber. Atmospheric equilibration of the chamber is provided through a capillary vent that has its distal end in the liquid media. Equilibration of the chamber results in flow of atmospheric air into the capillary tube and subsequent egress of bubbles in the liquid media of the device indicates proper functioning of the dual lumen tube.

Intended Uses/Indications:

The SightSure[®] Operation Indicator is indicated for use as an accessory to a dual lumen gastrointestinal sump tube with an air vent lumen which allows for a visual monitor of proper functioning of the tube during medical use.

Physical/ Mechanical Specifications:

The device is characterized by a chamber that is filled with sterile water prior to use. Negative pressure provided by a functioning dual lumen medical tube vent lumen is applied to the chamber through a tube linking the vent (sump) lumen to the sealed chamber. Atmospheric equilibration of the chamber is provided through a capillary vent that has its distal end in the liquid media. Equilibration of the chamber results in flow of atmospheric air into the capillary tube and subsequent egress of bubbles in the liquid media of the device indicates proper functioning of the dual lumen tube.

Biological Specifications:

This SightSure Operation Indicator is non-patient contact and does not require testing per ISO 10993.

Materials:

The product is manufactured with components primarily made of styrene and vinyl.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2000

MEDevices, Inc.
c/o Ms. Michele H. Vovolka
President
Vantage Consulting International, Ltd.
P.O. Box 848
Grayslake, IL 60030

Re: K993358
SightSure Operation Indicator - for use with a
dual lumen gastrointestinal sump tube
Dated: January 21, 2000
Received: January 24, 2000
Regulatory Class: II
21 CFR §876.5980/Procode: 78 KNT

Dear Ms. Vovolka:

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 legally marketed predicate 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 Current Good Manufacturing Practice requirements, 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) 594-4591. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K993358

Device Name: SightSure Operation Indicator

Indications For Use:

The SightSure® Operation Indicator is indicated for use as an accessory to a dual lumen gastrointestinal sump tube with an air vent lumen which allows for a visual monitor of proper functioning of the tube during medical use.

(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)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993358