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510(k) Summary
Georgia BioMedical, Inc.
Filter Heater/Hydrator Insufflation Gas Conditioner

JAN 23 1998

1. SUBMITTED BY

Georgia BioMedical, Inc.
250 Charter Lane
Macon, Georgia 31210

CONTACT PERSON

Douglas E. Ott, M.D.
Georgia BioMedical, Inc.
250 Charter Lane
Macon, Georgia 31210

DATE PREPARED

July 1, 1997

2. DEVICE NAME

Filter Heater/Hydrator Insufflation Gas Conditioner

CLASSIFICATION NAME

Laparoscopic Insufflator

CLASSIFICATION STATUS

The Filter Heater/Hydrator Insufflation Gas conditioner (21 CFR 884.1730, Product Code 85HIF) has been classified under Section 513 of the Act as Class II by the Obstetrical and Gynecological Devices Panel.

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3. PREDICATE DEVICES

WISAP Op-Pneu subject of K941438, the WISAP Flow-Therme subject of K952508, the CO_2Guard™ Insufflator Filter Tubing, Georgia BioMedical, Inc. subject of K920205 and the Snowden-Pencer Insufflator subject of K920986.

4. INTENDED USE

The Georgia BioMedical Filter Heater/Hydrator Insufflation Gas Conditioner is an accessory to an insufflator intended to heat, humidify and filter a gas stream used for inflation during laparoscopic surgery.

5. DEVICE DESCRIPTION

The Filter Heater/Hydrator Insufflation Gas Conditioner is a single use device which attaches to the outlet port of an insufflator and is designed to warm and humidify the gas stream prior to insufflation. The device consists of a universal gas connector, a control module which houses the control and safety circuits for the system and a disposable filter heater/humidifier (FHH) tubing set.

Gas from the insufflator is routed into the FHH tubing set via the control module. Within the filter heater/humidifier tubing set particles >0.3 μm in size are filtered from the gas, the gas is heated to 35°C and the gas is hydrated to $>80\%$ relative humidity. The distal end of the filter heater/humidifier tubing set terminates in a Luer lock connection for attachment to a gas entrance port for the abdomen, pleural space, chest cavity, abdominal cavity or any other body cavity.

7. PERFORMANCE TESTING

Testing was performed to evaluate the time required for the Filter Heater/Hydrator Insufflation Gas Conditioner to heat the gas after the device is first activated. The data shows a temperature of 36°C is reached within 100 seconds of activation, demonstrating that the heating element in the Filter Heater/Hydrator Insufflation Gas Conditioner rapidly warms the insufflation gas to body temperature after activation.

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Testing was performed to determine the effect of flow rate on the relative humidity of the conditioned gas. Gas was allowed to flow at a rate of 1 liter per minute for 2-5 minutes, at which time the humidity at the outlet port of the FHH tubing set was recorded. This procedure was repeated for flow rates of 3,5,6 and 8 liters/minute. The data shows that a relative humidity of >80% can be maintained with flow rates of at least 8 liters/minute.

Testing was performed to determine the effect of the FHH tubing set, with and without the presence of humidification fluid, on gas pressure. The results of this testing indicate only a very slight reduction in gas pressure produced by the proposed Filter Heater/Hydrator Insufflation Gas Conditioner. This reduction in gas pressure increases with flow rate. Humidification of the FHH cassette does not increase the pressure drop observed, even at high rates of gas flow.

Testing was performed to demonstrate the maintenance of humidity of the conditioned gas. The testing was performed under worst case conditions, at a high flow rate and under-humidification. The results suggest that at use conditions of an 8 cc water charge and moderate flow rates, the capacity of the system is adequate to humidify the 180 liter volume of gas specified by the manufacturer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 1998

Georgia Biomedical, Inc.
c/o Cynthia J. M. Nolte, Ph.D.
Associate Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K970866
Laparoscopic Filter Heater/Hydrator Insufflation Gas Conditioner (Georgia Biomedical, Inc.)
Dated: October 24, 1997
Received: October 27, 1997
Regulatory class: II
21 CFR §884.1730/Product code: 85 HIF

Dear Dr. Nolte:

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 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) 594-4613. 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970866

Device Name: Filter Heater/Hydrator Insufflation Gas Conditioner

Indications For Use:

The Georgia BioMedical Filter Heater/Hydrator Insufflation Gas Conditioner is an accessory to an insufflator intended to heat, humidify and filter a gas stream used for inflation during laparoscopic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Robert R Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970866