

NOV 20 1998



15220 N.E. 40th Street
P.O. Box 97013
Redmond, Washington 98073-9713
425-882-3700

K981530

510(k) SUMMARY

Spacelabs Medical 90519 Anesthesia Delivery System

1. Submitter's Name/ Contact Person: Russ Garrison
Company: Spacelabs Medical Inc.
15220 N.E. 40th Street
Redmond, WA 98073
Telephone: (425) 882-3913
Facsimile: (425) 867-3550
2. Name of Device: Spacelabs Medical 90519 Anesthesia Delivery System
Classification: Gas-Machine, Anesthesia
73BSZ; 868.5160
Class II
3. Predicate Device: We consider the Spacelabs Medical 90519 Anesthesia Delivery System to be substantially equivalent to currently-marketed devices with the identical intended uses. Specifically, the Spacelabs Medical 90519 Anesthesia Delivery System is substantially equivalent to the Falcon marketed by Medical and Industrial Equipment Limited (MIE) (510[k] reference K971030) for the administration of general anesthetics, continually or intermittently, and to maintain a patient's ventilation.
4. Device Description: The Spacelabs Medical 90519 Anesthesia Delivery System is designed to deliver anesthetic gases in a controlled hospital environment.

The System incorporates a valveless patient circuitry design which offers very low resistance during spontaneous breathing since it allows for the ebb and flow of natural breathing. Oxygen, nitrous oxygen, and air are supplied to the gas distribution system for mixing with the selected anesthetic agent and delivery to the patient through the ventilation system. Another circuit separately provides for the cycling of patient expiration gases.

gases.

The operator may select from two operating modes options: in manual mode the patient can be ventilated manually via a hand bag or the patient can breathe spontaneously; alternately, the controls can be set so that the patient is continually ventilated by the device.

The control settings provide ease of use for both pediatric and adult patient populations in that the System may be set by the anesthesiologist for the appropriate tidal volume range based on patient needs. . The System uses standard, commercially-available anesthesia system accessories appropriate to meet the needs of the clinician and patient.

The delivery of gases is time cycled, volume controlled, pressure limited, and monitored for alarm states and error messages. Additional user-selectable convenience features include a hold switch to permit the temporary cessation of mechanical (continual) ventilation to facilitate the taking of imagery (e.g. x-rays) and a "sigh" switch to provide extra volume above the set tidal volume at a defined interval to allow for the more complete expiration of carbon dioxide.

5. Intended Use

The Spacelabs Medical 90519 Anesthesia Delivery System provides intermittent or continuous gas inhalation for adults and children (neonatal and pediatric). It allows the administration of operator selected gas mixtures of oxygen, nitrous oxide and air with any of the anesthetic agents: Halothane, Isoflurane, Enflurane, or Sevoflurane. It provides safe and accurate gas flows to maintain patient respiration during anesthesia, and incorporates a ventilator, an oxygen monitor, and a respiratory monitor. The ventilator provides the necessary power, as air or oxygen, to generate volumes and pressures in the ventilating system to ventilate a patient connected to the anesthesia machine. It is recommended for use only by trained physicians, in the operating room or similar surgical environments.

6. Comparison of Technological Characteristics

The intended use, design, materials, accessories, energy source, and principles of operation are similar to the Falcon Anaesthesia System. Both systems utilize a "bag in bottle" technology to provide fresh and anesthetic gases and to control the ventilation cycle. Both systems offer the convenience for use in both pediatric and adult patients by user adjustment of the tidal volume range

control to the appropriate mode setting. Both units are time cycled, volume controlled, and pressure limited at user-selectable settings, generating alarms and error messages as appropriate.

The Spacelabs Medical 90519 Anesthesia Delivery System differs from the Falcon in offering a valveless patient circuitry to provide a low resistance pathway for the delivery of fresh gas to the patient. The 90519 System additionally features the capabilities for user selection of a "sigh" capability for more complete expiration of CO₂ gas, a "hold" feature to temporarily maintain a breath to reduce patient motion during a photographic (e.g. x-ray) session, and the automated calculation and display of monitored parameters such as resistance and minute volume for user convenience.

7. Standards

The Spacelabs Medical 90519 Anesthesia Delivery System is designed to meet the general safety requirements for medical equipment, including the requirements of UL2601-1, C222.2 No. 601-1, IEC 601-1 and IEC-1-2. The 90519 also meets the requirements of industry standards for anesthesia delivery systems, including ASTM, EN, and ISO Standards. The device will be CE marked as a Class IIB device to the Medical Devices Directive.

8. Testing

The Spacelabs Medical 90519 Anesthesia Delivery System has been subject to extensive safety and performance testing, to ensure that the device meets all of its functional requirements and performance specifications. Safety and standards testing has been, or will be, performed by third party agencies to ensure the System complies to applicable industry and safety standards.

In conclusion, the Spacelabs Medical 90519 Anesthesia Delivery System is as safe and effective as its predicate device and raises no new issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1998

Ms. Nancy Gertlar
Spacelabs Medical, Inc.
15220 N.E. 40th Street
P.O. Box 97013
Redmond, WA 98073-9713

Re: K981530
Spacelabs Medical 90519 Anesthesia Delivery System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: August 27, 1998
Received: August 28, 1998

Dear Ms. Gertlar:

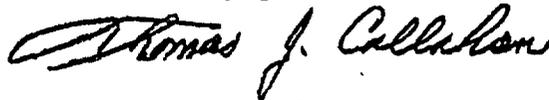
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not Known (New Submission) **K981530**

Device Name: Spacelabs Medical 90519 Anesthesia Delivery System

Indications for Use:

The Spacelabs Medical 90519 Anesthesia Delivery System provides intermittent or continuous gas inhalation for adults and children (neonatal and pediatric). It allows the administration of operator selected gas mixtures of oxygen, nitrous oxide and air with any of the anesthetic agents: Halothane, Isoflurane, Enflurane, or Sevoflurane. It provides safe and accurate gas flows to maintain patient respiration during anesthesia, and incorporates a ventilator, an oxygen monitor, and a respiratory monitor. The ventilator provides the necessary power, as air or oxygen, to generate volumes and pressures in the ventilating system to ventilate a patient connected to the anesthesia machine. It is recommended for use only by trained physicians, in the operating room or similar surgical environments.

(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)

Muller
11/19/98
Lawe Mada *11-17-98*
Muller

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____