OCT 7 - 2004

K041430

510(K) SUMMARY
(as required by 807.92(C))

Submitter of 510(K):	Blease Medical Equipment Ltd. Deansway, Chesham Bucks, England HP5 2NX Phone +44 1494784422 Fax +44 1494 791497
Contact Person:	Richard Cooke
Date of Summary:	Thursday, 29 January 2004
Trade Name:	Blease Frontline Sirius 2000, 3000
Classification Code:	BSZ
Classification Name:	Anaesthesia Gas Machine
Predicate Device:	Blease Frontline Plus K003251 Blease 6200 Ventilator K982132
Device Description/ Comparison:	The Frontline Sirius is similar to the cleared Frontline Plus anaesthesia machine and the 6200 ventilator. The size and shape of the cabinet are the different, but the pneumatic systems and ventilator are the same.
Intended Use:	The Blease Frontline Sirius Range, Anaesthesia Machines are intended for use in the hospital environment and operating room. It may be used for the delivery of oxygen, air, and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of a mechanical ventilator, and may be used for the delivery of anaesthetic vapour by use of a dismountable vaporizer. The device is intended for use only by a suitably qualified physician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Blease Medical Equipment Limited
C/O Mr. Arthur J. Ward
AJW Technology Consultants, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K041430
Trade/Device Name: Blease Frontline Sirius Range, Anaesthesia Machine
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: September 2, 2004
Received: September 30, 2004

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

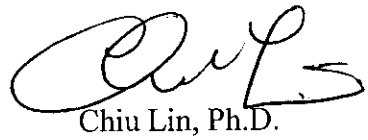
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041430

Device Name: Blease Frontline Sirius Range, Anaesthesia Machine

Indications for Use:

Blease Frontline Sirius Range, Anaesthesia Machines are intended for use in the hospital environment and operating room. It may be used for the delivery of oxygen, air and nitrous oxide in a controlled manner to various patient breathing circuits with or without the use of mechanical ventilator, and may be used for the delivery of anaesthetic vapour by use of a dismountable vaporizer.

The device is intended for use only by a suitably qualified physician.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041430

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)