



NOV 3 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Henry Marshall
Medical Industrial Equipment Ltd.
Falcon Road,
Sowton Industrial Estate
Exeter, Devon, EX2 7NA
ENGLAND

Re: K981845
Hawk™ Anaesthesia Induction Unit
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: October 9, 1998
Received: October 13, 1998

Dear Mr. Marshall:

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.

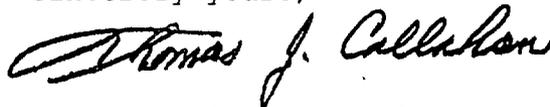
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice 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.

Page 2 - Mr. Henry Marshall

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

510(k) Number (if known): K981845

Device name: The MIE Hawk Anaesthesia Induction Unit

Indications For Use:

The Hawk Anaesthesia Induction Unit is a medical device for providing continuous gas inhalation for adults and children above 5 kg body weight. It facilitates the control and administration of operator selected gas mixtures with anaesthetic agents. The anaesthetic agents are accurately dispensed by a suitable anaesthetic vaporiser, of the type specified, which may be safely and securely attached to the modular backbar.

The Hawk provides safe and accurate gas flows to maintain patient respiration during induction of anaesthesia. It is specified for use with an oxygen monitor and other suitable monitoring, these monitors are specified in the operator's manual.

The Hawk may be safely used with magnetic resonance imaging systems (MRI) as it is MRI compatible.

It is recommended that pre-use checks and preparation is done by suitably qualified technicians, and that the device is used only by trained and qualified physicians. The device is used in the induction room, operating room, recovery 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)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981845

Prescription Use
(Per 21 CFR 801.109)

OR

Over The Counter Use

(Optional Format 1-2-96)