



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 10 2000

Mr. Michael Fisher
Safety Coordinator
General Air Service & Supply
6330 Colorado Boulevard
Commerce City, Colorado 80022

Re: K993789
Trade Name: Clinical Blood Gas Mixture
Regulatory Class: II
Product Code: CHL
Dated: October 26, 1999
Received: November 9, 1999

Dear Mr. Fisher:

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.

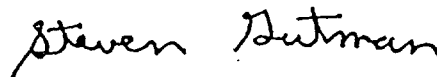
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

A handwritten signature in dark ink, reading "Steven Gutman". The signature is fluid and cursive, with the first name "Steven" and last name "Gutman" clearly distinguishable.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GENERAL AIR

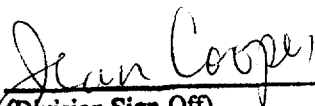
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510 (k) NUMBER (IF KNOWN): K993789

DEVICE NAME: Clinical Blood Gas Mixture

INDICATIONS FOR USE:

Clinical Blood Gas Mixtures are intended for use as calibration gases for ~~research and~~
Blood Gas Analyzers.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993789

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use ☐
(Optional Format 1-2-96)

BOULDER, CO 80301-2524
3750 WALNUT STREET
(303) 444-2138
FAX (303) 440-7730

DENVER, CO 80204-3399
1105 ZUNI STREET
(303) 892-7003
FAX (303) 595-9036

FT. COLLINS, CO 80524-2723
1918 HEATH PKWY.
(970) 221-0697
FAX (303) 572-8256

GREELEY, CO 80631-5931
1700 1ST AVENUE
(970) 353-5224
FAX (303) 825-0906

LITTLETON, CO 80120
4901 RIO GRANDE
(303) 797-0204
FAX (303) 797-0649

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