



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2006

Mr. Matthew Thie
Ameriflo Corporation
478 Gradle Drive
Carmel Industrial Park
Carmel, Indiana 46032

Re: K060382

Trade/Device Name: Flo-Rite, Flo-Rite II, Neumatix, Simpulse and Simpulse II
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous ventilator
Regulatory Class: II
Product Code: NFB
Dated: March 16, 2006
Received: March 21, 2006

Dear Mr. Thie:

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.

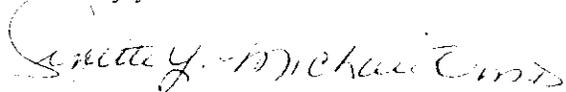
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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



478 Gradle Dr. • Carmel Industrial Park • Carmel, IN 46032 • 800-976-2390 • 317-844-2019 • Fax 317-844-7164 • www.ameriflo.com

Indications for Use

510(k) Number (if known): K060382

Device Name: Flo-Rite, Flo-Rite II, Nuematix, Simpulse and Simpulse II.

Indications for Use: The Flo-Rite Conserving Device Regulator is intended for prescription use only, to be used in conjunction with a portable oxygen tank for supplemental oxygen therapy for in home or ambulatory application.

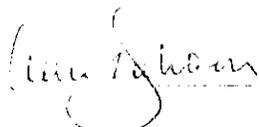
Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRII, Office of Device Evaluation (ODE)



Jim Johnson
Director, General Hosp.
Medical Devices
 K060382

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