SUMMARY OF SAFETY AND EFFECTIVENESS K974372

FEB - 5 1998

1. Name: SK MED

Address: 16000 Sherman Way #224
Van Nuys
CA 91406

Phone: (818) 785-8349

FAX: (818) 785-8349

Contact: Dipak Ghosh

Date: June 28, 1997

2. Device Name:

Air Oxygen Mixer

3. Predicate Device:

The **Bird Low Flow Air/Oxygen Microblender** is a predicate device that has been on the market since the early 1970's.

4. Description of the Device:

The Air Oxygen Mixer is a pneumatically controlled low flow (up to 30 lpm maximum flow) air oxygen mixing device.

5. Intended Use:

The Air Oxygen Machine has the same intended use as the predicate device i.e. the Bird Air Oxygen Microblender. It is used to provide respiratory care in conjunction with:

- Oxygen Hoods
- Resuscitation Bags
- Masks
- Nasal Cannulas

6. Technology Characteristics:

Mixer: The Air Oxygen Mixer, like the Bird Low Flow Microblender, uses 2 pneumatic pressure regulators and a mechanical mix valve to control oxygen concentration in the delivered gas mixture.

Alarms: The **Air Oxygen Mixer** uses two pressure switches to monitor air and oxygen supplies. If either air or oxygen or both gas supplies fall below a specified threshold, appropriate **audio-visual alarms** are activated. There is a dedicated LED indicator for low air and low oxygen supply pressure resp. The LEDs are powered by a 9 Volt battery. The battery itself is monitored by a low voltage indicator LED.

The **Bird Low Flow Microblender** activates an audio alarm if the air and oxygen supply pressures differ by more than 20 PSIG. There is no indication of which gas supply is low. Moreover, *if both supplies are low, there is no alarm at all.*

Testing:

In order to verify Safety, Effectiveness (performance), and Environmental Characteristics (including Hi/Lo Temperature, Humidity, Shock/Vibration), the Air Oxygen Mixer was subjected to extensive bench & environmental laboratory testing. The results of the testing have demonstrated that the **Air Oxygen Mixer is as safe and effective as the Bird Low Flow Microblender.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 1998

Mr. Dipak Ghosh
SK Med
16000 Sherman Way #224
Van Nuys, CA 91460

Re: K974372
Air Oxygen Mixer
Regulatory Class: II (two)
Product Code: 73 BZR
Dated: November 19, 1997
Received: November 20, 1997

Dear Mr. Ghosh:

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 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/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): K974372

DEVICE NAME: AIR OXYGEN MIXER

FEB. 2, 1998

INDICATIONS FOR USE:

The SK Med Air Oxygen Mixer is intended for use with the infant and pediatric population in a hospital environment. Its indications for use are exactly the same as the predicate device i.e. the Bird Low Flow Air Oxygen Microblender. It is used to provide oxygen therapy in conjunction with:

- Oxygen Hoods
- Resuscitation Bags
- Masks
- Nasal Cannulas

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

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

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K974372