AUG 10 1999

K992503

510(K) SUMMARY
7-13-99

Device Name:

Classification Name:	Breathing gas mixer
Common Name:	Gas Mixer
Proprietary Name:	Sechrist Air-Oxygen Mixer

Devices to which Equivalence is Claimed: Sechrist Air-Oxygen Mixer K802226

Contact: Greg Godfrey, Vice President
Quality Assurance & Regulatory Affairs
4225 E. La Palma Avenue
Anaheim, CA 92807
Phone: (714) 579-8400 Fax: (714) 579-0814

Indication for Use

The intended use of the device is to enable qualified personnel to mix medical grade air and medical grade oxygen, at operator selected ratios, for delivery to patients through various types of respiratory care equipment.

Device Description

The Sechrist Series 3500HL Air-Oxygen Mixer is a precision pressure regulation and proportioning device which is designed to mix medical air with medical oxygen, for delivery to patients through a variety of respiratory care equipment.

The mixer receives air and oxygen at a nominal 50 psi via Diameter Index Safety System (D.I.S.S.) inlet connections. The unit will operate satisfactorily with inlet pressures of 30 to 70 psi providing the pressures are within 20 psi of one another.

Two outlets for the mixed gas are provided. One is located on the side of the unit for the convenient connection of a flowmeter. The second outlet may be used to power other respiratory or cardiopulmonary care equipment requiring a controlled FIO_2.

The air-oxygen mixers are configured with zero to three flowmeters. Accessories include air and oxygen hoses. Flowmeters may also be purchased separately.

Performance Standards

A performance standard regulation under Section 514 of the Food, Drug and Cosmetic Act has not been promulgated for this device type. However, the device is designed and manufactured in accordance with the following national and international standards:

ISO 9001	Quality Assurance Standard
ISO 13485	Quality System Medical Devices
EN 46001	Application of ISO 9001 to manufacturer of medical devices
21CFR820	Quality Systems Regulation

Summary of Substantial Equivalence

Flowmeter options were added to enable the user to adjust and control the gas flow rate. Additional specifications, not specified in the original 510(k), were also added to the *User's Manual* and include the following: high and low flow mixer specifications, nominal supply pressure, and bleed flows for high and low flow mixer configurations. There have been no changes in the material, technology, or intended use of the device.

Conclusion

Modifications made to the cleared device include flowmeter options and corresponding labeling changes made to the *User's Manual* that were not contained in the original 510(k). These changes do not affect the intended use or alter the fundamental scientific technology of the device. Therefore, the modified device is substantially equivalent to the cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 1999

Mr. Greg Godfrey
Sechrist Industries, Inc.
4225 E. La Palma Avenue
Anaheim, CA 92807

Re: K992503
Air-Oxygen Mixer
Regulatory Class: II (two)
Product Code: 73 BZR
Dated: July 23, 1999
Received: July 27, 1999

Dear Mr. Godfrey:

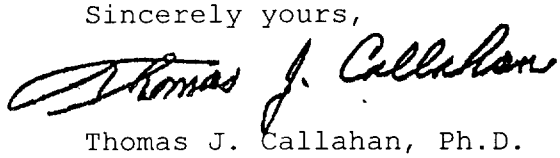
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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

Indications for Use Statement

K992503

510(k) Number (if known): K802226

Device Name: Sechrist 3500/3500HL Series Air-Oxygen Mixer

Indications for Use:

The purpose of the device is to enable qualified personnel to mix medical grade air and medical grade oxygen, at operator selected ratios, for delivery to patients through various types of respiratory care equipment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J. A. Westerhausen 8.10.99

Prescription Use ✓ **OR** **Over-The-Counter** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number _____

(Optional Format 1-1-96)