JAN 11 2000

K990856

510(K) SUMMARY

SoftAire Nasal CPAP System

Bird Products Corporation

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June 18, 1999

K990856

General Information

Device Trade Name: **SoftAire Nasal CPAP System**

Device Common/Classification Name:

The SoftAire Nasal CPAP System is Bird Products Corporation ventilator classified under 73 BZD "Non-Continuous Ventilator"

- **868.5905** Non-Continuous Ventilator, 73 BZD

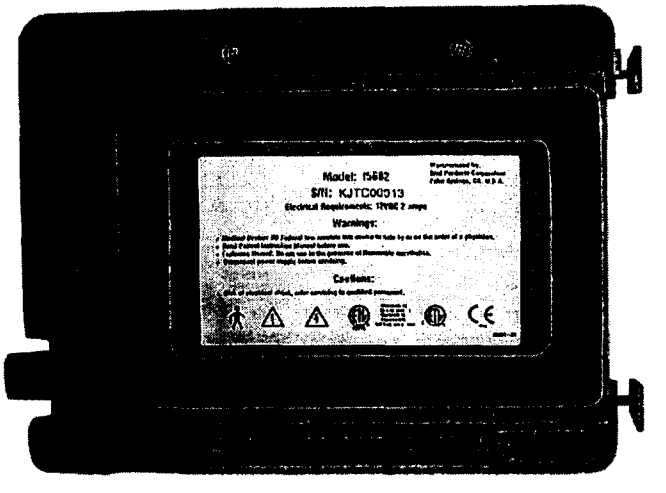
Predicate Device: ResMed Sullivan III Nasal CPAP System
FDA 510(k) No: 930656

Year 2000 Compatibility: The SoftAire Nasal CPAP System does not perform any date calculation or processing and is therefore year-2000 compliant.

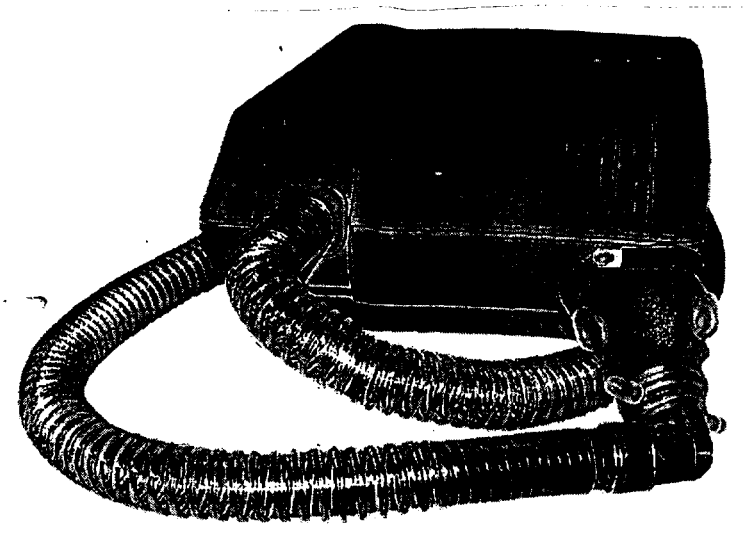
Device Description

The SoftAire Nasal CPAP System is intended to provide continuous positive airway pressure for the care and treatment of individuals suffering from obstructive sleep apnea. The positive pressure is clinician adjustable within the designated operating range and a clinician adjustable timer will allow timed rise to pressure ("Ramp" mode). The user controls will be limited to an on/off switch and option of using the timed pressure rise. This product is designed to be used with a 22 millimeter (smooth bore) tube air delivery system and user selected nasal mask. This mask is not marketed by Bird.

Power will be provided by AC to DC adapter s which accommodate a variety of input voltages and frequencies. This adapter will plug into a 12 VDC connector on the side of the unit.



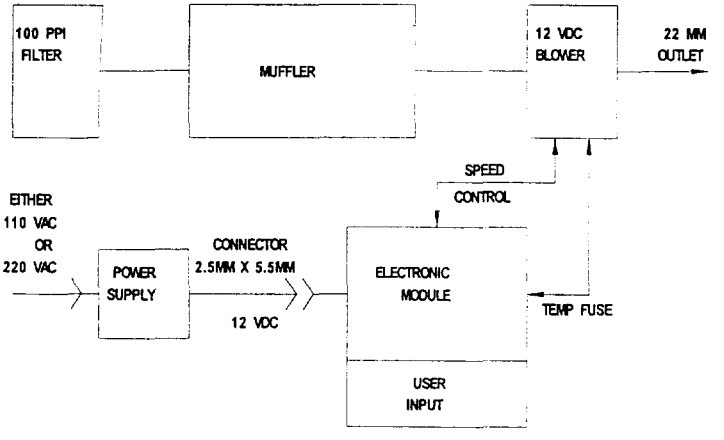
Bottom View of SoftAire Nasal CPAP System



SoftAire Nasal CPAP System with tube and nasal mask.

The SoftAire Nasal CPAP System does not utilize an actively controlled exhalation valve. The patient circuit consists of two essential parts: a large-bore tube from the ventilator to the patient and a required exhaust port. The exhaust is an orifice which may be part of the adapter between the tubing an the patient mask, or may be an orifice which is part of the patient mask.

Electrical/Pneumatic System



Flow to the patient is provided via 12 VDC Brushless Motor driving an impeller. Air intake passes through a filter and muffler into the motor, which operates at a preset speed established by the (clinical) operator. Patient tubing pressure is verified by an independent pressure measurement.

An external 12-Volt power source supplies a 5-Volt regulator, which provides power to all interval components. The CPU runs at 4 MHz. There are 5 switches underneath the unit for Mode, Plus, Minus, "Ramp Mode On" and "Ramp Mode Off".

Comparison to Predicate Device

The SoftAire Nasal CPAP System is not significantly different from the predicate device, the ResMed Sullivan III Nasal CPAP, first cleared for market under 510(k) K930656. Both devices utilize Blower type flow generators with the Bird SoftAire Nasal CPAP having a maximum working pressure of 22cmH_2O.

Summary of Performance Testing

Performance testing was conducted in the laboratory to confirm operation compliance to the device specifications. Testing to Environmental, EMI/RFI and Electrical Safety Standards were performed by certified test facilities. The following table specifies all SoftAire Nasal CPAP functions. All functions were verified to operate as designed and intended, as denoted by the checkmark.

Specification	Requirement	
Adjustable Therapeutic Pressure Range	4-18 cmH_2O.	☑
Adjustable Beginning Pressure Range	4 and 18 cmH_2O and below therapeutic range.	☑
Pressure Accuracy	±10% to the nearest displayed digit (claibrated at 500ft elevation)	☑
Timer	0, 5, 10, 15, 20 minutes, ±2 minutes	☑
Input Voltage	12 ±10% VDC, 2A	☑
Noise Level	< 38dB	☑
Dimensions	11X8X4 inches	☑
Weight	5.2 lb	☑
Tubing	6 ft, 22mm female connectors	☑
Electrical Safety	EN 60601-1	☑
EMI/RFI	EN 60601-1-2 & Draft Reviewers Guidance for Ventilators 1995	☑
Environmental	IEC 68-2	☑
Operating Temperature	+10 to +40°C, 30 to 75% RH	☑
Storage Temperature	-20 to +60°C, up to 95% RH	☑

Performance testing verified that the SoftAire Nasal CPAP meets all of it's performance requirements and that this device is substantially equivalent to medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2000

Mr. Tom Gutierrez
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262

Re: K990856
SoftAire Nasal CPAP System
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: October 13, 1999
Received: October 14, 1999

Dear Mr. Gutierrez:

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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990856

Device Name: SoftAire Nasal CPAP System

Indications for Use:

The nasal CPAP unit is intended for treatment of adult Obstructive Sleep Apnea (OSA). Obstructive sleep apnea is defined as the absence of air movement for ten seconds during sleep. Obstructive sleep apnea is usually diagnosed by a sleep study. The study obtains the optimum level of pressure required to maintain an unobstructed airway, the positive pressure allows the airway to stay open. The nasal CPAP unit is intended only for spontaneously breathing adult patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF REQUIRED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990856

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional format 1-2-96)