K983643

OCT 29 1998

SAFETY AND EFFECTIVNESS STATEMENT.

TRADE NAME: Genesis® BLS Resuscitator

COMMON NAME: AUTOMATIC RESUSCITATOR

REGULATORY CLASS: II

510K # : TO BE SUPPLIED

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED:

GENESIS® II A/C - 510K #: K932170

DESCRIPTION OF THE DEVICE:

The Genesis® BLS automatic/manually triggered resuscitators are designed to provide respiratory support to patients in either respiratory arrest or respiratory distress.

The device incorporates the features of Automatic Ventilation and Manual Ventilation into a single handpiece design that is a derivative of the Genesis® II Adult/Child device. The device is totally pneumatic in its function therefore requiring no batteries or other power sources apart from a compressed gas supply of either air or oxygen (as specified by the customer) and a regulated output from the gas source between 50 and 90 psi.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

This device is designed to meet the ever changing needs of the emergency respiratory care market.This device is similar in terms of features to the Genesis® II product - 510K # K932170 except in the removal of the demand breathing and auto shut off functions.

ASSESSMENT OF PERFORMANCE DATA

The submission incorporated a significant amount of non-clinical test data to support the claim of substantial equivalence. This test data reviewed the performance of the device against both the current domestic and international standards for these devices.

In particular, references were made to ISO 8382-1988.

CONCLUSIONS BASED ON PERFORMANCE DATA

The testing undertaken verified that the Genesis® II BLS device, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

CONTACT PERSON: KEVIN BOWDEN,
DIRECTOR OF PRODUCT TECHNOLOGY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

Mr. Kevin Bowden
O-Two Systems International Inc.
7575 Kimbel Street
Mississauga, Ontario
Canada L5S 1C8

Re: K983643
Genesis® BLS
Regulatory Class: II (two)
Product Code: BTL
Dated: October 15, 1998
Received: October 16, 1998

Dear Mr. Bowden:

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

510K Number (if known):

Device Name: GENESIS® BLS RESUSCITATOR

Indications for Use:

[] Pulmonary resuscitation during respiratory and/or cardiac arrest.

[] Short term ventilatory support for both inter and intra-hospital transport of non-breathing patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983643

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

(Optional Format 1-2-96)