

4/22/99

K991195

## **SAFETY AND EFFECTIVENESS STATEMENT.**

**TRADE NAME:** CAREvent BLS Resuscitator

**COMMON NAME:** AUTOMATIC RESUSCITATOR

**REGULATORY CLASS:** II

**510K # :** TO BE SUPPLIED

**LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED:**

GENESIS® BLS - 510K #: K983643

**DESCRIPTION OF THE DEVICE:**

The CAREvent 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 BLS 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® BLS - 510K #: K983643 except in the addition of an extra automatic setting and the change of the manual ventilation mode to manual override of the automatic cycling, allowing the selection of a range of flowrates for manual ventilation in line with the size of patient being resuscitated.

**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 CAREvent BLS device, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

**CONTACT PERSON:** KEVIN BOWDEN,  
GENERAL MANAGER  
O-TWO SYSTEMS INTERNATIONAL INC.  
7575 KIMBEL STREET  
MISSISSAUGA  
ONTARIO  
CANADA  
L5S 1C8

TEL: 905 677 9410  
FAX: 905 677 2035  
E-MAIL: kevinb@otwo.com

# **SAFETY AND EFFECTIVENESS STATEMENT.**

**TRADE NAME:** CAREvent ALS 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 CAREvent ALS 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 addition of an extra automatic setting and the change of the manual ventilation mode to manual override of the automatic cycling, allowing the selection of a range of flowrates for manual ventilation in line with the size of patient being resuscitated.

**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 CAREvent ALS device, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

**CONTACT PERSON:** KEVIN BOWDEN,  
GENERAL MANAGER  
O-TWO SYSTEMS INTERNATIONAL INC.  
7575 KIMBEL STREET  
MISSISSAUGA  
ONTARIO  
CANADA  
L5S 1C8

TEL: 905 677 9410  
FAX: 905 677 2035  
E-MAIL: kevinb@otwo.com

# **SAFETY AND EFFECTIVNESS STATEMENT.**

**TRADE NAME:** CAREvent BLS<sup>+</sup>

**COMMON NAME:** AUTOMATIC RESUSCITATOR

**REGULATORY CLASS:** II

**510K # :** TO BE SUPPLIED

**LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED:**

Autovent 1000 510K #: K983785

## **DESCRIPTION OF THE DEVICE:**

The CAREvent BLS<sup>+</sup> is an automatic time cycled resuscitator designed to provide respiratory support to patients in either respiratory arrest or respiratory distress.

The device incorporates the features of Automatic and Manual Ventilation into a control module with separate hose and patient valve

This device is identical in terms of features to the Autovent 1000 - 510K #: K983785 with the addition of the ability to select the manual flowrate with a flowrate equivalent to that selected on the tidal volume/frequency control.

## **SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The device is a pneumatically powered, 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.

The device is a time-cycled ventilator with a range of 12, pre-set, automatic settings in which both the tidal volume and frequency of ventilation are adjusted simultaneously by the rotation of a vertically mounted rotary control. A manual button is provided to enable the operator to control the patient's breathing parameters with a flowrate equivalent to that selected on the tidal volume/frequency control.

The patient's airway is protected by an over pressure alarm, pre-set to 60 cmH<sub>2</sub>O, which gives an audible signal of over pressure and vents the remaining tidal volume

delivery for that breath to atmosphere.

## **ASSESSMENT OF PERFORMANCE DATA**

The predicate device 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 international standard for these devices - ISO 8382-1988.

## **CONCLUSIONS BASED ON PERFORMANCE DATA**

The testing undertaken verified that the CAREvent BLS<sup>+</sup> resuscitator, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

**CONTACT PERSON:** KEVIN BOWDEN,  
GENERAL MANAGER  
O-TWO SYSTEMS INTERNATIONAL INC.  
7575 KIMBEL STREET  
MISSISSAUGA  
ONTARIO  
CANADA  
L5S 1C8

TEL: 905 677 9410  
FAX: 905 677 2035  
E-MAIL: kevinb@otwo.com

# **SAFETY AND EFFECTIVENESS STATEMENT.**

**TRADE NAME:** CAREvent ATV

**COMMON NAME:** AUTOMATIC TRANSPORT VENTILATOR

**REGULATORY CLASS:** II

**510K # :** TO BE SUPPLIED

**LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED:**

Autovent 1500 - 510K #: K983857

**DESCRIPTION OF THE DEVICE:**

The CAREvent ATV is an automatic time cycled ventilator designed to provide respiratory support to patients in either respiratory arrest or respiratory distress.

The device incorporates the features of Automatic Ventilation, Manual Ventilation, and Demand Breathing into a control module with separate hose and patient valve.

This device is identical in terms of features to the Autovent 1500 product - 510K # K983857 with the addition of independent minute volume and frequency controls, adjustable pressure relief, 60/100% air/oxygen mix and the ability to select the manual flowrate with a flowrate equivalent to that selected on the minute volume control. An additional alarm feature has also been added to warn of low input pressure.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The device is a pneumatically powered, 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.

The device is a time-cycled ventilator with a range of 12, automatic frequency settings and 12 minute volume settings which are both adjusted by the rotation of a vertically mounted rotary control. A manual button is provided to enable the operator to control the patient's breathing parameters with a flowrate equivalent to that selected on the minute volume control.

Should the patient commence spontaneous breathing while being ventilated, their inspiratory effort will cause the device to provide breathing on demand while simultaneously causing the automatic cycling to cease. Should the patient cease to breathe spontaneously the automatic cycling will recommence without intervention by the operator being necessary.

The patient's airway is protected by an over pressure alarm (adjustable from 20 to 60 cmH<sub>2</sub>O), which gives an audible signal of over pressure and vents the remaining tidal volume delivery for that breath to atmosphere.

### **ASSESSMENT OF PERFORMANCE DATA**

The predicate device 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 international standard for these devices - ISO 8382-1988.

### **CONCLUSIONS BASED ON PERFORMANCE DATA**

The testing undertaken verified that the CAREvent ATV, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

**CONTACT PERSON:** KEVIN BOWDEN,  
GENERAL MANAGER  
O-TWO SYSTEMS INTERNATIONAL INC.  
7575 KIMBEL STREET  
MISSISSAUGA  
ONTARIO  
CANADA  
L5S 1C8

TEL: 905 677 9410  
FAX: 905 677 2035  
E-MAIL: kevinb@otwo.com



# **SAFETY AND EFFECTIVENESS STATEMENT.**

**TRADE NAME:** CAREvent ALS<sup>+</sup>

**COMMON NAME:** AUTOMATIC RESUSCITATOR

**REGULATORY CLASS:** II

**510K # :** TO BE SUPPLIED

**LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED:**

Autovent 1500 - 510K #: K983857

**DESCRIPTION OF THE DEVICE:**

The CAREvent ALS<sup>+</sup> is an automatic time cycled resuscitator designed to provide respiratory support to patients in either respiratory arrest or respiratory distress.

The device incorporates the features of Automatic Ventilation, Manual Ventilation, and Demand Breathing into a control module with separate hose and patient valve.

This device is identical in terms of features to the Autovent 1500 product - 510K # K983857 with the addition of the ability to select the manual flowrate with a flowrate equivalent to that selected on the tidal volume/frequency control.

**SUMMARY OF TECHNOLOGICAL CHARACTERISTICS**

The device is a pneumatically powered, 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.

The device is a time-cycled ventilator with a range of 12, pre-set automatic settings in which both the tidal volume and frequency of ventilation are adjusted simultaneously by the rotation of a vertically mounted rotary control. A manual button is provided to enable the operator to control the patient's breathing parameters with a flowrate equivalent to that selected on the tidal volume/frequency control.

Should the patient commence spontaneous breathing while being ventilated, their inspiratory effort will cause the device to provide breathing on demand while

simultaneously causing the automatic cycling to cease. Should the patient cease to breathe spontaneously the automatic cycling will recommence without intervention by the operator being necessary.

The patient's airway is protected by an over pressure alarm, pre-set to 60 cmH<sub>2</sub>O, which gives an audible signal of over pressure and vents the remaining tidal volume delivery for that breath to atmosphere.

## **ASSESSMENT OF PERFORMANCE DATA**

The predicate device 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 international standard for these devices - ISO 8382-1988.

## **CONCLUSIONS BASED ON PERFORMANCE DATA**

The testing undertaken verified that the CAREvent ALS<sup>+</sup>, when compared with the performance of the device to which substantial equivalence is claimed, performed within specification.

**CONTACT PERSON:** KEVIN BOWDEN,  
GENERAL MANAGER  
O-TWO SYSTEMS INTERNATIONAL INC.  
7575 KIMBEL STREET  
MISSISSAUGA  
ONTARIO  
CANADA  
L5S 1C8

TEL: 905 677 9410  
FAX: 905 67 2035  
E-MAIL: kevinb@otwo.com



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 22 1999

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

Re: K991195  
CAREvent BLS, CAREvent BLS<sup>+</sup>, CAREvent ALS, CAREvent ALS<sup>+</sup>, and  
CAREvent ATV  
Regulatory Class: II (two)  
Product Code: 73 BTL  
Dated: April 6, 1999  
Received: April 8, 1999

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.

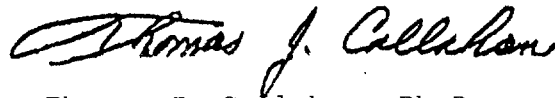
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Kevin Bowden

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: CAREvent 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)

*Arthur A. Carls*  
 (Division Sign-Off)  
 Division of **Cardiovascular, Respiratory,**  
 and Neurological Devices  
 510(k) Number \_\_\_\_\_  
 Over-The-Counter Use \_\_\_\_\_

Prescription Use   
(Per 21 CFR 801.109)

OR

**510K Number (if known):**

**Device Name:** CAREvent BLS<sup>+</sup> 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) \_\_\_\_\_

Prescription Use   
(Per 21 CFR 801.109)

OR

\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Serial Number \_\_\_\_\_  
Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

**510K Number (if known):**

**Device Name:** CAREvent ALS 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) \_\_\_\_\_

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

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

510K Number (if known):

Device Name: CAREvent ALS+ 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)

\_\_\_\_\_ Concurrency of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

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

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)



**510K Number (if known):**

**Device Name:** CAREvent ATV

**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) \_\_\_\_\_

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

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)