Traditional 510(k) Submission for the 2300 Series mGO Portable Oxygen Generator (Concentrator)

Section 5

510(k) Summary

Author			
Written By	**Title**	**Signature**	**Date**
Callum Berryman	Mechanical Engineer		24 April 2014

Approval			
Approved By	**Title / Department**	**Signature**	**Date**
A.N. Chilton	New Products Manager		24 April 2014
John Evans	Quality Engineer / Quality Assurance Department		24 April 2014

Revision History		
Document Version	**Reason for Update**	**Date**
01	Official issue	23rd December 2013
02	paras 5.1.3 & 5.1.5 amended; additional predicate device reference added ("SAROS 3000, K083163")	24th April 2014

5 Scope

This document details the 510(k) Summary for the 2300 Series mGO Portable Oxygen Generator (Concentrator) and constitutes part of Ultra Electronics Precision Air & Land System's Traditional 510(k) submission.

There have been no prior submissions for the 2300 Series mGO Portable Oxygen Generator (Concentrator).

5.1 510(k) Summary

This 510(k) summary has been prepared in accordance with the requirements of 21 CFR Part 807, Section 807.92 Content and Format of a 510(k) Summary. Responses to 807.92 (a) sections (1) to (6) and 807.92 (b) sections (1) to (3) are detailed below:

5.1.1 Submitter's Information

Submitter's Name	Ultra Electronics Limited Precision Air & Land Systems
Submitter's Address	Arle Court Hatherley Lane Cheltenham GL51 6PN United Kingdom
Telephone Number	Phone: 44 (0) 1242 221166 (Switchboard) Fax: 44 (0) 1242 221167
Contact Person	Alistair Barker Alistair.Barker@ultra-pals.com
Summary Preparation Date	24 April 2014 (Issue 2)

5.1.2 Product Information

Proprietary Name:	2300 Series mGO Portable Oxygen Generator (Concentrator)
Common Name:	2300 Series mGO
Classification of Device:	Portable Oxygen Generator
	Class II
Classification Panel	Anesthesiology
CFR Regulation Number	21 CFR 868.5440
Panel Code	CAW

5.1.3 Predicate Device(s)

Ultra Electronics Limited Precision Air & Land Systems claims equivalence to the following legally marketed predicate device:

Company Name	DeVilbiss Healthcare
Trade Name	iGO Portable Oxygen Generator
Model Number	306 Series
Contact Name	Joseph E. Olsavsky
510(k) Number	K081468

The 2300 Series mGO Portable Oxygen Generator is a ruggedized development of the 306 Series iGO Portable Oxygen Generator that uses many components common with the 306 Series iGO. The 2300 Series mGO Portable Oxygen Generator has been created with the full co-operation and support of DeVilbiss Healthcare.

Ultra Electronics Limited Precision Air & Land Systems claims equivalence to a second legally marketed predicate device, cleared to operate in a similar environment, as follows:

Company Name	SeQual Technologies Inc.
Trade Name	SAROS 3000 (aka OMNI 2 Oxygen System)
Model Number	OMNI 2
Contact Name	Brian Jarrell
510(k) Number	K083163 (Oct 20 2009)

5.1.4 Description

The 2300 Series mGO Portable Oxygen Generator delivers supplementary oxygen to casualties and patients at the point of need, eliminating the need for oxygen cylinders. It is designed to function in harsh environments for military users and agencies engaged in humanitarian and relief operations.

The 2300 Series mGO administers supplemental oxygen at a concentration of 93% ± 3% to USP32. The 2300 Series mGO can deliver oxygen at flow rates between 1 and 3 litres per minute (L/min), continuous flow, or, in pulse dose mode, an oxygen bolus of up to 84 millilitres (ml) (14 ml multiplied by the setting value, maximum of 6) equivalent to a continuous flow of 6 L/min in response to breath demand. This is termed Pulse Oximetry.

The 2300 Series mGO is based on the pressure swing adsorption (PSA) principle. The 2300 Series mGO delivers supplemental oxygen for patients through molecular sieve beds and is designed to conserve the use of oxygen in pulse dose mode. In pulse dose mode, oxygen is delivered to the patient through a pulse dose valve when a patient starts to inhale.

Ambient air is drawn into the generator via a piston style compressor. The air first passes through a series of filters that remove dust, and other particulate matter before entering the compressor.

A poppet-style solenoid valve directs air into one of two sieve beds. Nitrogen is adsorbed in the bed as the pressure increases, while oxygen flows out of the sieve bed, thereby producing a highly enriched oxygen product. Simultaneously, in the second sieve bed, nitrogen is desorbed as the pressure decreases to a vacuum and is exhausted into the atmosphere. The cycle continues by alternately swapping the absorption/desorption process from one sieve bed to the other, providing a flow of oxygen to a receiver and the patient through a bacteria filter.

The 2300 Series mGO consists of pneumatic and electrical components, a pressure and vacuum compressor, a pressure vessel, Synthetic Zeolite molecular sieve beds, two lithium ion batteries, dust separator and particulate inlet filter, valve assemblies, an outlet bacteria filter, electronic flow control, touch control pad, a cooling fan assembly, and audible/visual alarms.

The 2300 Series mGO operates from 100-240 Volts AC mains power, 24-28 Volts DC power or two removable rechargeable batteries. The 2300 Series mGO may be carried manually (weight <10Kg) and transported by military or civilian vehicles on land, air and sea.

The device is provided with a 4.76 mm hose tail that is used to attach a cannula tube.

5.1.5 Statement of Intended Use

The 2300 Series mGO Portable Oxygen Generator is 1-3 L/min continuous (1-6 L/min Pulse Flow), pressure vacuum swing adsorption, supplemental oxygen concentrator, based on molecular sieve technology. The patient typically receives the oxygen through a nasal cannula.

The device is not intended for life support, nor does it provide any patient monitoring capabilities.

The device is intended for use in environments found in medical facilities, military deployment situations or disaster areas for humanitarian relief.

A Physician has prescribed a specific oxygen flow setting to meet an individual's needs. Oxygen flow settings should be adjusted only under the direction of a Physician.

Warning: Federal Law restricts this device to sale by or on order of a Physician.

Type of use: ☒ Prescription Use (Part 21 CFR 801 subpart D)

5.1.6 Comparison of Device Technological Characteristics to Predicate Device

As the 2300 Series mGO is a development of the predicate 306 Series iGO, in terms of technological characteristics, it is identical. However there are differences at a detail level. For Substantial Equivalence Discussion – *See Section 12.*

In order to make the 2300 Series mGO more suited for use by the military or in disaster areas, some changes had to be made to the predicate device. The changes involved in the development of the 2300 Series mGO Portable Oxygen Generator, from the DeVilbiss Healthcare 306 Series iGO, are; ruggedizing the structure and housings, reducing the overall size and changing the shape to long and slender as opposed to rectangular. None of these developments have altered the technological characteristics of operation. The 2300 Series mGO has a fundamentally similar architecture.

Ruggedizing:

The case material for the 2300 Series mGO is a vacuum cast, fire retardant (UL94 V-0), Polyurethane whereas the 306 Series iGO case material was Noryl grade PX1005X. The change to the case material itself was to suite lower volume production methods rather than to ruggedize however the two case materials are a close equivalent in terms of mechanical properties. The design of the case has given it additional strength compared to the predicate due to additional internal webs. In addition the shape has significantly reduced the size of any flat panel areas compared to the predicate device.

Added protection has been provided by the fitting of bump strips along each exposed edge of the case and additional mouldings at each at each end to protect the case from bumps and drops. The material of all the added bump protectors is again fire retardant (UL94 V-0) Polyurethane but it has an elastomeric nature to absorb the shocks when bumped or dropped.

A high air flow fan has been fitted and heat sinks have been added to strategic electrical components to improve the cooling of the 2300 Series mGO over the 306 Series iGO.

Vortex filters have been added and mesh screens improved to decrease the ingress of contamination through the cooling air inlet.

Sealed electrical connectors have been used and the PCB assemblies given conformal coatings to prevent damage from water and general impurity, and the sealing of the outer housing has been improved to better equip the 2300 Series mGO to tolerate sand, dust and water damage.

Reducing the Overall Size

The main pcb has been approximately halved in size by using a 6 layer PCB for the 2300 Series mGO as opposed to the original 2 layer PCB for the 306 Series iGO. The circuit and functionality remains the same for both devices.

For the 2300 Series mGO the overall space taken up by the 2 separate sieve bed filter columns and one O_2 reservoir has been reduced by combining the 3 items into one using a single aluminium extrusion with the 3 chambers within it. This enabled the cross section of the sieve bed filter columns and reservoir to be non-cylindrical and the 3 items to be closely nested, with the required shape and without wasting an space between them. Apart from the change of cross section and a change of length the volumes, amounts of sieve material used, operating function and method remains the same.

Smaller, higher energy density, batteries have been used in the 2300 Series mGO. However the battery capacity is similar in both this and the predicate device and the battery technology is Lithium Ion in both cases.

Changing the Shape

The case shape of the 306 iGO was rectangular but the 2300 Series mGO is required to be a long slender shape so that: it can be mounted in places where a "D" sized oxygen cylinder has previously been fitted, it can be carried on a stretcher/litter either between a patient's leg or beside them.

Other Changes

The software from the Predicate Device, 306 Series iGO Portable Oxygen Generator, has been imported to the 2300 Series mGO Portable Oxygen Generator. However, due to the differences in operating environments of the 2300 Series mGO compared to the 306 Series iGO, some small changes to the software were made. These changes consist of: removing the "automobile adapter" power scheme (there is no requirement for the 2300 Series mGO to operate from 12 Volt DC Vehicles) and widening of the temperature calibration table for the oxygen sensing device.

An additional "battery communications" software feature has been incorporated into the 2300 Series mGO Portable Oxygen Generator. This software resides on a separate Printed Circuit Board (PCB) and its purpose is to translate between the industry standard SMBus protocol used by the off the shelf battery packs and the custom battery protocol used by the main PCB.

A simple software program has been added to change the brightness of the control panel LEDs. This software is covered by its own set of documentation and testing.

A low temperature cut out threshold has been added to the motor control PCB on the 2300 Series mGO. This was added to ensure that an open circuit fault of the thermistor would be detected (a high temperature threshold was already present). Apart from this and the addition of a heat sink, the motor control PCB is identical to that of the predicate device.

5.1.7 Nonclinical Tests

The 2300 Series mGO has been tested in accordance with the requirements of the following specifications and standards:

IEC 60601-1:1988	Medical electrical equipment - Part 1: General requirements for safety – Collateral standard – Safety requirements for medical electrical systems. Includes amendments A1, A11 and A12
IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.
ISO 8359:2009 +A1:2012	Oxygen concentrators for medical use – Safety requirements (ISO 8359:1996).

The majority of the non-clinical testing has been carried out by Intertek Testing and Certification Limited, a recognised notified body for medical equipment.

A summary of the non-clinical tests and the conclusions is provided in the table below:

Nonclinical Test:	**Test Summary**	**Test Conclusions**
ER2486 – Qualification Test Report: EMC & electrical safety	This reports on the Electromagnetic Compatibility (EMC) and the Electrical Safety testing conducted in accordance with the requirements of IEC 60601-1-2: 2007 on the 2300 Series mGO. These tests were performed by Intertek.	The 2300 Series mGO has passed all EMC and electrical safety tests performed by Intertek for emissions and immunity. The test results conclude that the 2300 Series mGO will not interfere with its environment to a dangerous level, and is immune to any electrical interference which may affect its intended operation.
ER2487 – Qualification Test Report: Basic Safety Tests to IEC 60601-1:1988	This reports on the Safety testing conducted in accordance with the requirements of IEC 60601-1:1988 on the 2300 Series mGO. These tests were performed by Intertek.	The 2300 Series mGO passed all the requirements of these tests.
ER2499 – Oxygen enrichment during system leakage analogy	This report examines the potential for an Oxygen Rich Environment to exist under failure conditions of the 2300	The worst case Oxygen concentration is 22.66% caused by O_2 leakage from the O_2 reservoir. This is safely below

Nonclinical Test:	Test Summary	Test Conclusions
	Series mGO in areas containing potential ignition sources. and therefore that IEC 60601-1:2005 Paragraph 11.2.2 does not apply to the 2300 Series mGO.	the 25% limit that defines an Oxygen Rich Environment. An Oxygen Rich Environment cannot therefore exist in the 2300 Series mGO in areas containing potential ignition sources, therefore IEC 60601-1:2005 Paragraph 11.2.2 does not apply in the case of the 2300 Series mGO.
ER2501 – Sieve bed life analogy report	Through analogy and read across from accelerated filter bed life testing on the predicate device and from extended life testing conducted on the 2300 Series mGO, this report examines the long term effects on the Accumulator & Filter Housing Assembly in 2300 Series mGO and establishes it's service life.	There is no evidence to suggest that the performance of the sieve column assembly (drg. No. 2300-4347) will degrade with time. After 2010 hours of continuous running without significant change in performance. A service life of 1000 hours can be given.
ER2502 – Compressor seal life analogy report	Through analogy and read across from the compressor life testing conducted on the predicate device, this report examines the predicted life of the compressor seals for the 2300 Series mGO. This is possible because the 2300 Series mGO uses the same compressor under the same operating conditions as the predicate device.	The compressor seals in the 2300 Series mGO will have a service life in excess of 10,000 hours.
ER2503 – Relief valve life analogy report	This report details, through analogy with relief valve testing conducted on the predicate device, the predicted life of the pressure relief valve built into the 2300 Series mGO. This is	Based on the evidence shown in this report, the pressure relief valve in the 2300 Series mGO will have a life of at least 100,000 cycles.

Nonclinical Test:	Test Summary	Test Conclusions
	possible because the 2300 Series mGO uses the same relief valve with the same opening pressure as the predicate device.	
ER2507 – Outlet Gas Purity analogy report	This report evaluates, by analogy, the Outlet Gas Purity of the 2300 Series mGO, against volatile organic compounds (VOC), carbon dioxide (CO_2), carbon monoxide (CO), Ozone (O_3) and fine particulate matter, to ensure that it does not contribute or add any of these to the oxygen stream to the patient.	This evaluation concludes, by analogy, that the 2300 Series mGO will not contribute VOCs, CO, CO_2, O_3 or fine particulate matter to the output stream. Results from all test parameters indicated lower (or non-detected) concentrations of target analytes in the Oxygen Generator process stream than were observed in ambient intake air. These results are based on the tests conducted on the 306 Series iGO, as reported in I-2489 (appendix A), and apply equally to the 2300 Series mGO.
ER2580 – Filter / Accumulator pressure test report	This report details the pressure tests, and results thereof, conducted on the Accumulator & Filter Housing Assembly (Part No. 2300-4347) fitted in the 2300 Series mGO.	The Accumulator & Filter Assembly met the requirements of IEC 60601-1:2005 Paragraph 9.7.5 "Pressure Vessels". It sustained a pressure of 75 psig (3 times its maximum working pressure under single fault conditions) without burst, permanent deformation or leakage.
ER2650 – Extended Life Test Report	This report describes the methodology, equipment and test results of extended life testing on the 2300 Series mGO with the intention of investigating any degradation in the performance or materials.	The extended life test is currently operating at 3778 hours and shows no sign of further degradation or failure. There have been two failures so far, the first is a known issue, corrected during assembly processes, and the second occurred at 1.8 times the recommended service life. After

Nonclinical Test:	Test Summary	Test Conclusions
		the second failure at 1840 hours, the 2300 Series mGO has continued to run for over 1900 hours with no further failures. Regarding the Mechanical Pressure Regulator and Pressure Transducer, they have both exceeded the 100,000-cycles test requirement for IEC 60601-1 approval.
ER2689 – Fire Mitigation Test to ISO 8359 Amendment A1:2012	This test report documents the results from verification testing carried out to demonstrate that the 2300 Series mGO O_2 outlet connection (DRG No. 2300-4274) prevents a flame from propagating back through the outlet into the oxygen concentrator, in accordance with section 56.12 of ISO 8359 Amendment A1:2012.	The aluminium O_2 outlet connection prevented the flame from propagating back into the oxygen concentrator.
ER2695 – Oxygen tubing and cannula flow test report	The 2300 Series mGO is designed to deliver oxygen to the patient via a nasal cannula. This report defines the tests conducted, and results thereof, to establish that the 2300 Series mGO operates correctly with the maximum length of oxygen tubing specified in the IFU.	The 2300 Series mGO Portable Oxygen Generator operated to specification, in both continuous and pulse dose modes, when fitted with the maximum tubing lengths specified in the Instructions for Use (2300-4388).

5.1.8 Clinical Tests

No clinical tests have been submitted – *see Attachment 20, Performance Testing - Clinical,* where report number ER2493 "Clinical Evaluation by Analogy" concludes that a clinical evaluation is not required because oxygen therapy is mature and because of substantial equivalence with the predicate device.

5.1.9 Conclusion

The 2300 Series mGO Portable Oxygen Generator (Concentrator) is substantially equivalent to the predicate devices listed in this Summary and the device does not raise any new issues of safety and/or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Ultra Electronics
Precision Air & Land Systems
Ian Bradley
Head of Management System/Quality Assurance Dept.
Arle Court Hatherley Lane
Cheltenham Gloucestershire
GL51 6PN England

Re: K134023
Trade/Device Name: 2300 Series mGO Portable Oxygen Generator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: March 28, 2014
Received: March 28, 2014

Dear Mr. Bradley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Erin I. Keith
Acting Division Director
Division of General Hospital, Respiratory,
Anesthesiology Infectious Control, and Dental
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K134023

Device Name
2300 Series mGO Portable Oxygen Generator

Indications for Use *(Describe)*

The 2300 Series mGO Portable Oxygen Generator is 1-3 L/min continuous flow (1-6 L/min Pulse Flow), pressure vacuum swing adsorption, supplemental oxygen concentrator, based on molecular sieve technology. The patient typically receives the oxygen through a nasal cannula.

The device is not intended for life support, nor does it provide any patient monitoring capabilities.

The device is intended for use in environments found in medical facilities, military deployment situations or disaster areas for humanitarian relief.

A Physician has prescribed a specific oxygen flow setting to meet an individual's needs. Oxygen flow settings should be adjusted only under the direction of a Physician.

WARNING: Federal Law restricts this device to sale by or on order of a Physician

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

For Anya Harry MD PhD

James J. Lee

Digitally signed by James J. Lee
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=James J. Lee, 0.9.2342.19200300.100.1.1=2000954859
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