K113338

510(K) Summary

AUG 10 2012

Submitter:	Oricare, Inc. 1900 AM Drive, Suite 100 Quakertown, PA. 18951
Contact Person:	David Jamison, Executive Vice President, Oricare, Inc. Phone: 215-538-2470
Date Prepared:	October 19, 2011
Device Trade Name:	C4500 Medical Air Compressor
Name: Common / Usual:	Medical Air Compressor
Classification Name:	Compressor, Air, Portable
Predicate Device:	EKOM DK50D Medical Compressor
Predicate 510(k) #:	K060781
Regulation Number:	21CFR868.6250
Product Code:	BTI

Substantial Equivalence Summary

The C4500 Medical Compressor is substantially equivalent in intended use, physical characteristics, performance, and safety characteristics to the EKOM DK50K, cleared under #K060781.

Intended Use:
This air compressor can be used as a gas supply for a critical care ventilator.

Indications for Use:
The Oricare C4500 Medical Air Compressor is indicated to supply dry filtered and compressed air to a Medical Ventilator that operates within the C4500 Compressor manufacturer specifications.

Device Description:
The Oricare C4500 Medical Air Compressor operates from an AC Voltage source and produces air from the normal environment to supply compressed air for medical ventilators.

Device Testing
Comprehensive testing has been conducted on C4500 Medical Air Compressor in accordance with various industry recognized standards, including: IEC 60601-1:1988 +a1:1991, +A2:1995 and IEC 60601-1-2:2007. Additionally, Air Quality Testing, Life Testing, and Storage and Transportation testing were performed. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

Comparison to Predicate Device

#	Item of comparison	EKOM DK50 D Medical Compressor (K060781)	Oricare C4500 Air Compressor	Discussion of the differences
1.	Intended use of the device	The DK50 D Medical Compressor is indicated for supplying compressed air for medical ventilators.	This air compressor can be used as a gas supply for a critical care ventilator.	No differences
2	Indications for use	The EKOM DK50 D, DK50 DM is indicated for use as medical air compressor to supply a source of clean, oil-free pressurized air for use with medical ventilators.	The Oricare C4500 Medical Air Compressor is indicated to supply dry filtered and compressed air to a Medical Ventilator that operates within the C4500 Compressor manufacturer specifications.	No differences
3	Environment of Use	Medical Care Facilities	Medical Care Facilities	No Differences
4	Principle of operation	Compression, cooling, drying and filtering of oil-free air	Compression, cooling, drying and filtering of oil-free air	No Differences
5	Output flow/pressure	40 l/min at 51 psig	40 l/min at 50 psig	No Differences
6	Peak Flow	200 pm for 2 sec	Peak Flow 180 Lpm for 0.6 sec	No Differences
7	Power	120V /60 Hz	Power 115V /60 Hz	AC Mains line voltage varies from 103VAC to 127VAC. Both systems are within the range.
8	Power consumption	5.6 A	Nominal current (amps) <600VA	Oricare device consumes slightly less power meaning it is slightly more efficient.
9	Overcurrent Protection	Fuses	Circuit Breakers	Oricare product provides more convenient for service

#	Item of comparison	EKOM DK50 D Medical Compressor (K060781)	Oricare C4500 Air Compressor	Discussion of the differences
10	Air filtration	5 micron	5 micron	No Difference
11	Pressure dew point	@ 40 Lpm 20°C - 5°C below ambient temperature	@ 40 Lpm 3°C below ambient temperature	No real discernible difference.
12	Outlet connection	DISS	1- DISS	No Difference
13	Sound level	< 51 dB(A)	< 52 dB(A)	No real discernible difference. The audible tone is for alarm annunciation purposes. An increase in the dB(A) would provide an advantage to user.
14	Mode of operation	Continuous - SI	Continuous - SI	No Difference
15	Separation of condensed water	Automatic	Automatic	No Difference
16 1	Operating pressure of safety valve	116 psig	65 psig	Device regulates pressure at 40 psig.
17	Adjustment of pressure	Pressure regulator	Pressure regulator	No Difference
18	Alarm for cooling failure / high	Acoustic and optical if increase in internal temperature > 80°C	Acoustic and optical if increase in internal temperature > 80°C	No Difference
19	Automatic turn-on pressure	When central distribution pressure < 40.6 psig	When central distribution pressure < 40.6 psig	No Difference
20	Output pressure	Pressure gauge	Pressure gauge	No Difference
21	Alarm - loss of power	No, but instructions require connection to equipment with this alarm	Yes	Advantage for Oricare product Safety

#	Item of comparison	EKOM DK50 D Medical Compressor (K060781)	Oricare C4500 Air Compressor	Discussion of the differences
22	Additional Visual Indicators	Not included	"AC Power" light "Ready" light – outlet pressure ready "Air Source – Wall" light	Safety Advantage for determining AC Mains Power is connected
23	Indication of drying	Pressure gauge	None	design includes chiller and external water trap to remove excess moisture.
24	Alarm for low pressure	None instructions require connection to equipment with this alarm	Yes, triggers when output pressure <25.4 psig	Oricare device does not rely on 3rd party device to be connected.
25	Material in gas pathway	Aluminum, brass, nickel plated brass, polyurethane and silicon tubing, copper tubing, Plastic (PA, PET, POM, PBT, PC, Acetyl, Polyester), polyurethane foam, NBR rubber, Stainless steel, die cast zinc	Aluminum, brass, nickel plated brass, polyurethane and silicon tubing, copper tubing, Plastic (PA, PET, POM, PBT, PC, Acetyl, Polyester, polyurethane foam, NBR rubber, Stainless steel, die cast zinc	No Difference
26	Air tank capacity	5L	2L	Excess capacity not needed to supply sufficient peak flow. Predicate device is larger because extra capacity requires additional weight and physical size.
27	Compressor Type	Oil free piston and ring- positive	Oil free wobble type rocker piston- positive	No Difference
28	Type of lubrication	Oil-less	Oil-less	No Difference

#	Item of comparison	EKOM DK50 D Medical Compressor (K060781)	Oricare C4500 Air Compressor	Discussion of the differences
29	Ambient Environment	41 to 104 degrees F; up to 95% RH	50 to 104 degrees F; 15 – 90% RH	Oricare device range is typical of many ventilators.
30	Dimensions	19(L)x20(W)x33(H) in	16.22 (L)x17.4(W)x15.75(H) in	Oricare device is smaller
31	Weight	101 lbs	66 lbs	Oricare device is lighter
32	Electrical Safety	EN 60601-1	IEC 60601-1:1988, +A1:1991, +A2:1995	No difference, both comply
33	Mechanical Safety	EN 60601-1	IEC 60601-1:1988, +A1:1991, +A2:1995	No difference, both comply

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 10 2012

ORICARE, Incorporated
Mr. Fred Cowdery
Manager Regulatory Affairs and Quality Assurance
1900 AM Drive, Suite 100
Quakertown, Pennsylvania 18951

Re: K113338
Trade/Device Name: C4500 Medical Air Compressor
Regulation Number: 21 CFR 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: July 31, 2012
Received: August 02, 2012

Dear Mr. Cowdery:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K113338U

Device Name: C4500 Medical Air Compressor

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for L. Scheithers

(Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K113338