DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 19,2014

HGI INDUSTIRES
Dr. Connie Araps
Chairman of HGI Scientific Advisory Board.
2055 High Ridge Road
Boynton Beach, FL 33426 US

Re: K133800
Trade/Device Name: ODOROX(R) MDU/RX (TM)
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical UV Air Purifiers
Regulatory Class: II
Product Code: FRA
Dated: November 17, 2014
Received: November 19, 2014

Dear Dr. Araps:

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,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection 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

Form Approved: OMB NO. 0910-0120
Expiration date: December 31, 2014

Indications for Use

510(k) Number K133800

Device Name

Odorox® MDU/Rx™

Indications for Use (Describe)

The MDU/Rx™ medical model is an ultraviolet (UV) air purifying device intended for the reduction of bacteria and the MS2 and Phi-X174 virus in air in medical facilities. The MDU/Rx™ medical device is non sterile.

Type of Use: [X] Over-the-counter use (21CFR 807 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)

510(k) Summary

510(k) Owner:	**HGI Industries, Inc.** **2055 High Ridge Road** **Boynton Beach, FL 33426** **Phone: 561-735-3701** **Fax: 561-347-3824**
Contact Person:	**Connie Araps, PhD** **2055 High Ridge Road** **Boynton Beach, FL 33426** **Phone: 561-735-3701** **Fax: 561-347-3824**
Date Prepared:	**December 15, 2014**
Proprietary Name(s):	**Odorox® MDU/Rx™**
Common Name:	**Air purifier ultraviolet or ultraviolet air purifier (used interchangeably by substantially equivalent devices)**
Trade Name:	**Odorox® MDU/Rx™**
Classification Name: **Purifier.**	**21 CFR 880-6500 Class II Medical Ultraviolet Air**
Product Code:	**FRA**
Category:	**General Hospital**

2055 High Ridge Road • Boynton Beach, FL 33426 • phone: 561.735.3701 • toll free: 877.735.3701 • fax: 561.735.3824 • www.hgiind.co

510(k) Summary

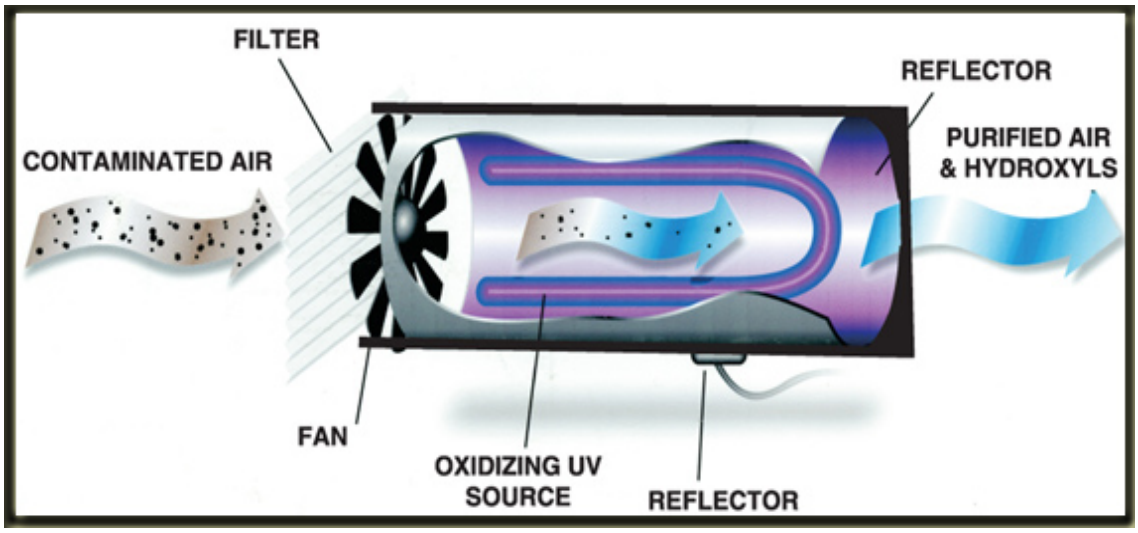
Intended Use

The MDU/Rx™ medical model is an ultraviolet (UV) air purifying device intended for the reduction of bacteria and the MS2 and Phi-X174 virus in air in medical facilities. The MDU/Rx™ medical device is non sterile.

Product Description

The MDU/Rx™ device purifies and sanitizes air by circulating ambient air through a filter into a chamber equipped with two ultraviolet (UV) lights (also called optics) with wavelengths in the range between ~100-285 nm, which encompasses the range of light called UV-C, as described in the general system design in Figure E-1.

Figure E-1 MDU/Rx™ Device General System Design



UV light in this range is commonly called germicidal. The radiation penetrates the cell walls of bacteria and virus and is absorbed by the organic structures within the cell, causing them to decompose and the cell to die.

General product information is provided below in Table E-1.

Table E-1 MDU/Rx™ Device Ultraviolet Air Purifier Product Information

MODEL #	PRODUCT NAME	DESCRIPTION	# Of OPTICS	Optic Model #
MDURXMA00	MDU/Rx™	MOBILE Air DISINFECTION UNIT, 120VAC	2	OPT-XX-176

The Odorox® MDU/Rx™ system is judged to be a Class II device that falls within the FDA category:

- Common name: ultraviolet air purifier or air purifier ultraviolet
- General Hospital
- Purifier, air, ultraviolet, medical
- Regulation Number: 880.6500
- Product Code: FRA

Substantial Equivalence

Based on the fact that the MDU/Rx™ system uses UV light with wavelengths of 100 – 285 nm that includes the range commonly called germicidal (or UV-C) as the means by which it sanitizes, the company believes that the system is substantially equivalent to the following FDA approved, legally marketed systems:

- **ECO-Rx AIR PURIFIER WITH UV LIGHT MODEL RX-400**
  - 510(k) Number: K062716
  - Regulation Number: 21 CFR 880.6500
  - Regulation Name: Medical Ultraviolet Air Purifier
  - Regulatory Class: II
  - Product Code: FRA
  - Decision: Substantially equivalent
  - Date Approved: 10/27/2006
  - Classification: General Hospital
  - Type: Traditional
  - Combination Product: No

- **RXAir 3000**
  - 510(k) Number: K951981
  - Regulation Number: 21 CRF 880-6500
  - Regulation Name: Medical Ultraviolet Air Purifier
  - Regulatory Class II
  - Product Code: FRA
  - Decision: Substantially equivalent
  - Date Approved: 10/27/2006
  - Classification: General Hospital
  - Type: Traditional
  - Combination Product: No

All three types of devices are self-contained systems with similar quartz UV-C optics and varying types of filters. The systems use integrated fans to circulate air through the filters to remove particulates and sanitize the air by exposure to UV-C radiation, which

kills airborne microorganisms. They have similar active components, design features and intended uses. They do not incorporate any other sanitizing components such as catalysts or electrical discharge. The use of filters in the MDU/Rx™ device is primarily for the purpose of keeping the optic surfaces clean and is not intended as a means of sanitizing air.

The MDU/Rx™, RXAir 3000 and Eco RX-400 systems have the same intended use as described in Table E2. They are ultraviolet (UV) air purifying devices intended for the reduction of bacteria and specific virus in air in medical facilities. The devices are non-sterile. The construction of the devices is essentially the same in that they all circulate air through metal or plastic cases in which utilize UV-C lights (also called optics). As the air passes through the photolysis chamber and is exposed to the UV-C light, the microorganisms absorb the radiation and are killed.[1] They differ in the types of filters that are used, as described.

The RXAir 3000 uses a single "germicidal" UV-C lamp to sanitize and a five-stage filter to remove particulates, volatile organic compounds and bacteria. The ECO Rx 400 uses three UV-C lamps (also called optics) to sanitize and has a filter to remove particulates.

A comparison of the MDU/Rx™ device and available predicate product feature information is provided in Table E-2, below and compares:

- Indications for use
- Intended use
- Materials of construction
- Elements of design
- Mechanism of action

Table E-2 Comparison of MDU/Rx™, RXAir 3000 and ECO RX-400 Features

Features	Odorox® Units	RXAir 3000	ECO RX-400
Indications for Use	UV Air sanitizer	UV Air Sanitizer	UV Air Sanitizer
Intended Use	Kill bacteria, virus in air	Kill bacteria, virus in air	Kill bacteria, virus in air
Mechanisms of action	UV light kills microorganisms	UV light kills microorganisms	UV light kills microorganisms
Elements of design	Fan circulates air through shielded chamber where UV light irradiates microorganisms	Fan circulates air through shielded chamber where UV light irradiates microorganisms	Fan circulates air through shielded chamber where UV light irradiates microorganisms
Particulate filter	Yes	Yes	Yes
Internal Fan	Yes	Yes	Yes
Germicidal UV	Yes	Yes	Yes
UV Optic type	Quartz UV-C	Quartz UV-C	Quartz UV-C
Wavelength range of UV radiation	~100-285 nm	~100-285 nm	~100-285 nm

Catalyst coated surfaces	No	No	No
Electric discharge	No	No	No
Chemical additives	No	No	No
Type and Materials of Construction	Quartz UV optics, Metal or plastic structural case and fan powered by electric motor	Quartz UV optics, Metal or plastic structural case and fan powered by electric motor	Quartz UV optics, Metal or plastic structural case and fan powered by electric motor

In summary, the available information for the predicates and data from HGI indicate that all three devices generate UV-C radiation using quartz optics. The radiation is directly absorbed by the bacteria and virus in air as they pass through the photolysis chamber. The microorganisms die as a result of radiation damage to the DNA and other organic structures within the organisms' cell wall. UV-C radiation also reacts with oxygen and water vapor in air to generate very low concentrations of hydroxyl radicals in the range of 0.1 parts per trillion to one part per billion. Hydroxyl radicals can react with the lipids and proteins in the cell walls of microorganisms (including bacteria and virus) within the radiation chamber and kills them, contributing to the sanitization process. Both mechanisms occur concurrently.

Performance

The MDU/Rx™ model is designed to treat areas of approximately 130 to 500 square feet that would have 8 to 10 foot ceilings (~1300 to 5,000 cubic feet of space). The system is operated by the use of an on-off switch which activates both optics and the fan. The fan is set at a fixed speed of ~150 cubic feet per minute. When in use, an indicator light on the outside of the case is lit. The recommended mode of action is to have the unit running continuously. Larger spaces require the use of longer treatment times and/or multiple machines. The unit recirculates ambient air continuously through the UV-C photolysis chamber, where it is sanitized. Operational use guidelines are provided to users in the form of an Owner's Manual and advise that the MDU/Rx™ model is intended for use in ventilated spaces of four or more exchange rates per hour. The length of time required to reach optimal sanitization varies as a function of the volume of space being treated, and the dynamics of what occurs within the treatment space including:

- Initial load of microorganisms
- Degree of contamination being introduced by patient activities, treatment etc.
- Movement of personnel/patients within the space
- Rates of ventilation

The device is intended to result in high kill rates of 4-5 log reduction of airborne bacteria and the MS2 and Phi-X174 virus of initial concentrations of 6 log 8 -10 CFU/cu ft. of air and is not intended to create a sterile environment.

The system uses commercially available 48 watt quartz optics as UV-C radiation sources. The 48 watt optic produces 10 watts of light at ~254 nm (at 100 hours of use). There is an indicator light to show that both optics are on and are functioning properly.

The fan speed is not critical to the operation of the system. Generally, operating the fan at ~ 150 cfm results in slightly faster elimination of bacteria and virus than higher fan speeds as the ambient air has increased residence time within the photolysis chamber. The device uses a washable polyester filter to remove particulates greater than 8 microns. The purpose of the filter is primarily to keep the optics clean. Placement of the units is not critical to performance. In general the unit is best placed near a wall at an angle so as to create a vortex around the room to be treated.

Intertek tested the MDU™ model (identical to the proposed MDU/Rx™ model) for compliance with the safety Standards listed below:

- Electrical safety – fans, ventilators using Standards 1 and 2
- Safety for Luminaires using Standard 3
- UV Safety using Standards 4 and 5

1. Standard for Safety for Electric Fans, UL 507-9th Edition, Dated 12/13/1000, with revisions through And including September 27, 2007.

2. Standard for Fans and Ventilators, CSA C22.2 No. 113-10. General Instruction NO 1-7, Dated March 2, 2010.
3. Standard for Safety – Luminaires – UL 1598, 3rd Edition, 9/17/2008 with revisions through and including 2/20/2009

4. UL Standard for Electrical Equipment for Measurement, Control and Laboratory use; Part 1: General requirements, UL 61010-1, 2nd Edition, dated 07/12/04 with revisions through and including 07/22/05

5. Canadian Standards Association C22.2 No. 250, 0-04, 2nd Edition, Dated 12/30/04 with revisions through and including 05/31/06

The Intertek report concluded that "…the MDU™ product covered by this report has been evaluated and found to comply with the applicable requirements" of the Standards referenced above." Based on the Intertek report, the MDU™ unit is ETL Listed (UL 507 and CSA C22.2).

Ozone and organic oxidation by-products are formed as a result of the irradiation of ambient water vapor and oxygen in air by UV-C radiation with a range of wavelengths between ~100-285 nm. Columbia Analytical Services (Simi Valley, CA) evaluated the MDU™ device (identical to the proposed MDU/Rx™ device) for the purpose of measuring the types and concentrations of organic oxidation by-products and ozone in a 1296 cubic foot test space and a 3656 cubic foot test space. Air samples were taken in hourly intervals for up to fifteen hours. In summary, the data indicated that:

- No carbon monoxide was detected above baseline levels
- Formaldehyde, acetaldehyde and other target aldehydes remained at or marginally above background concentrations
- No significant concentrations of oxidized volatile organic compounds (VOC) were formed
- Ozone reached a steady state concentration of ~19 ppb in the smaller chamber and ~14 ppb in the larger chamber. The highest oxidant levels resulted from

using both optics with the fan at the low setting. These are the settings used by the MDU/Rx™ device.

Additional ozone measurement were conducted by HGI in a range of typical, normally ventilated treatment areas (3-6 exchange rates per hour) representative of those found in medical facilities. Measurements were also made without ventilation. The spaces ranged from ~1190 to 4102 cubic feet (~130 sf to ~450 sf with 8-9 foot ceilings). Testing times varied from 3 to 24 hours. Ozone (total oxidant) levels remained below 50 ppb for all tests.

Mode of Action

The primary mode of action for the MDU/Rx™ unit and its predicates is to sanitize air as it passes through the photolysis chamber by direct exposure to UV radiation with wavelengths between ~100-285 nm. The primary bactericidal mode of action of UV-C radiation results from the penetration of radiation into the interior of the cell where it is absorbed by key biochemicals. The UV radiation damages the RNA, DNA and other organic moieties within the cell preventing cell replication and causing cell death.

A secondary mode of action results from the formation of hydroxyl radicals within the photolysis chamber by the action of UV-C radiation with oxygen and water vapor in ambient air. The hydroxyl radicals react rapidly (within a second) with the lipids and proteins on the surface of the cells, causing the contents of the cell to leak and the cell to die.

MDU/Rx™ Device Effectiveness as an Air Sanitizer

The efficacy of the MDU/Rx™ device as an air sanitizer was determined by measuring the kill rates of selected aerosolized bacteria and virus. Studies of the kill rates of the following aerosolized microorganisms by the MDU/Rx™ unit were done for HGI by Aerosol Research and Engineering Laboratories (ARE, Overland Park, Kansas). The testing was conducted in a 563 cubic foot sterile stainless steel test clean-room chamber into which specified concentrations of aerosolized bacteria and virus were introduced.

- Staphylococcus epidermidis – a gram positive bacterium used as an index organism for Staphylococcus aureus; considered as representative of its class

- Erwinia herbicola – a gram negative bacterium used as an index organism for Escherichia coli; considered as representative of its class

  (Note: E. coli was tried but it proved too fragile to remain viable in an aerosol long enough to establish a stable baseline.)

- MS2 virus – a bacteriophage that infects E.coli that is used as a surrogate for mammalian influenza

- Phi-X174 virus – a DNA based bacteriophage that infects E.coli that is used as a surrogate model for HIV, HCV

Controls were run to establish a stable baseline of aerosolized microorganisms. Kill rates were measured in triplicate at regular intervals by sampling air from the chamber

until a 4-5 log reduction in viable organism was measured. The MDU/Rx™ resulted in a 4 log or greater kill rate for all organisms tested within two hours.

Conclusion:
The performance testing demonstrates that the MDU/Rx™ medical device is substantially equivalent to the FDA approved claimed predicate devices, the RxAir 3000 and the ECO RX-400.

Footnotes

1. "The History of Ultraviolet Germicidal Irradiation for Air Disinfection", Nicholas G. Reed, Public Health Rep. 2010 Jan-Feb; 125(1): 15-27.