DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 8, 2017

Transformair, LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K161468
Trade/Device Name: Transformair Indoor Air Purifier
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: January 31, 2017
Received: February 1, 2017

Dear Dave Yungvirt:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161468

Device Name
Transformair Indoor Air Purifier

Indications for Use *(Describe)*
The Transformair Indoor Air Purifier, In Duct Model 16108 is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

Transformair Indoor Air Purifier, In Duct Model 16108 has been demonstrated to destroy Staphylococcus epidermidis, Escherichia coli, MS2, Phi-X174, Aspergillus Niger and Bacillus globigii entrained on the filter of the subject device under the following exposure conditions:

Organism	Name	Average Maximum log reduction /exposure time (hours)		
		Test temperature		
		45°F	72°F	110°F
Bacteria	Staphylococcus	4.88 / 24 hours	4.02 / 0.33 hours	4.20 / 0.33 hours
Bacteria	Escherichia coli	4.31 / 24 hours	4.79 / 24 hours	4.40 / 0.33 hours
Virus	MS2 bacteriophage	4.13 / 24 hours	4.25 / 24 hours	5.51 / 24 hours
Virus	Phi-X174	4.37 / 24 hours	4.37 / 24 hours	4.37 / 24 hours
Mold endospore	Aspergillus Niger	3.91 / 72 hours	3.99 / 72 hours	4.22 / 72 hours
Bacterial endospore	Bacillus globigii	4.11 / 72 hours	4.41 / 72 hours	4.41 / 72 hours

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Transformair Air Purifier

Submitter:

Company Name:	Transformair, Inc.
Company Address:	3802 Spectrum Blvd. Suite 143 Tampa, FL 33612
Telephone Number:	352-871-3803
Contact Person:	Jaya Rao
Date Prepared:	1/19/2017

Device:

Proprietary Name:	Transformair Indoor Air Purifier
Common or Usual Name:	Air purifier ultraviolet or ultraviolet air purifier
Classification Name:	Medical Ultraviolet Air Purifier
Regulation Number:	21 CFR 880.6500
Product Code:	FRA
Device Class:	Class 2
Category:	General Hospital

Predicate Device:

The predicate device is shown in the following table:

Table 1: Predicate Device

Predicate Device	ABRACAIR Air Cleaners QTZ300-60 and TI 100-30P
Manufacturer	Abracair, Inc.
510(k) Number	K052732
Regulation Number:	21 CFR 880.6500
Regulation Name:	Medical Ultraviolet Air Purifier
Regulatory Class	II
Product Code :	FRA
Review Panel:	General Hospital
Combination Product	No

Intended Use / Indications for Use:

The Transformair Indoor Air Purifier, In Duct Model 16108 is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation.

Transformair Indoor Air Purifier, In Duct Model 16108 has been demonstrated to destroy Staphylococcus epidermidis, Escherichia coli, MS2, Phi-X174, Aspergillus Niger and Bacillus globigii entrained on the filter of the subject device under the following exposure conditions:

Table 2. Transformair Lethality Testing Results

Organism	Name	Average Maximum log reduction /exposure time (hours) Test temperature		
		45°F	72°F	110°F
Bacteria	Staphylococcus epidermidis	4.88/ 24 hours	4.02 /0.33 hours	4.20 /0.33 hours
Bacteria	Escherichia coli	4.31/ 24 hours	4.79 /24 hours	4.40 /0.33 hours
Virus	MS2 bacteriophage	4.13/ 24 hours	4.25/ 24 hours	5.51/ 24 hours
Virus	Phi-X174 bacteriophage	4.37/ 24 hours	4.37/ 24 hours	4.37/ 24 hours
Mold endospore	Aspergillus Niger	3.91/ 72 hours	3.99/ 72 hours	4.22/ 72 hours
Bacterial endospore	Bacillus globigii	4.11/ 72 hours	4.41/ 72 hours	4.41/ 72 hours

The Transformair Indoor Air Purifier is for Over-The-Counter use.

Device Description:

Transformair® is a patented photo-electrochemical or photo-electrocatalyst (PEC) ultraviolet air purification technology that destroys bacteria in air in medical facilities. It consists of a pre-filter, black light lamps, and a catalytic filter coated with a photocatalyst. The Transformair device has a metal housing with electronic controls and outer dimensions of 28.5 inches by 21 inches by 12.25 inches that is installed in the duct of a buildings HVAC system. The Transformair device has a pre-filter and a chamber equipped with 6 low energy ultraviolet lights (UV-A), which emit light with wavelengths between 320-400 nm, and a catalytic filter that has a metal wire mesh and is coated with a TiO2 photo catalyst.

Technological Characteristics and Principles of Operation:

The Transformair Air Purifier is a medical ultraviolet air purifier unit that traps microorganisms on a filter where they are destroyed by UV photo-catalyzed generation of free radicals in the validated time periods. The air cleaning chamber consists of a metal housing that contains a non-woven polyester pre-filter, glass UV-A lamps (~320-400 nm), a non-woven polyester catalytic filter with a wire mesh and titanium dioxide (TiO2) coating. The metal housing has electronics that plug into a standard outlet (120/220 Volt) to power the UV-A lamps.

The Transformair Air Purifier destroys microbiological contaminants in the air through a photochemical reaction that produces hydroxyl free radicals when UV-A light rays are shone on the TiO2 catalytic surface. The Transformair Air Purifier also has a metal wire mesh on the catalytic filter to increase the flow of electrons and facilitate the photochemical reaction. This is referred to as a Photo-Electro-Catalytic or Photo-Electro-Chemical (PEC) reaction.

Substantial Equivalence:

The Transformair Air Purifier is substantially equivalent to the ABRACAIR Air Cleaner (K052732) since the devices have the same general intended use and similar indications, technological characteristics, and principles of operation. A reference table is provided below comparing the Transformair Air Purifier to the predicate.

TABLE 3: SUBSTANTIAL EQUIVALENCE COMPARISON CHART

Element of Comparison	**Transformair**	**ABRACAIR (K052732)**
Manufacturer	Transformair, Inc.	Abracair, Inc.
Device type	Medical Ultraviolet Air Purifier	Medical Ultraviolet Air Purifier

Element of Comparison	Transformair	ABRACAIR (K052732)
Regulation Number	21 CFR 880.6500	21 CFR 880.6500
Intended Use / Indications for Use	The Transformair Indoor Air Purifier, In Duct Model 16108 is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation. Transformair Indoor Air Purifier, In Duct Model 16108 has been demonstrated to destroy Staphylococcus epidermidis, Escherichia coli, MS2, Phi-X174, Aspergillus Niger and Bacillus globigii entrained on the filter of the subject device under the exposure conditions described in Table 2. The Transformair Indoor Air Purifier is for Over-The-Counter use.	The Abracair Air Cleaner is intended for the reduction of aerosolized mold and bacteria within hospitals, nursing homes, medical facilities. The device may be used in occupied spaces within hospital environments such as baby and/or neonatal nurseries, hospital rooms, operating rooms, mortuaries, embalming rooms.
Mechanism of action	UV light of sufficient energy (UV-A) activates photocatalyst that destroys microorganisms entrained on the filter through a photochemical reaction that is enhanced by a metal wire mesh.	UV light of sufficient energy (UV-C) activates photocatalyst that destroys microorganisms through a photochemical reaction; UV-C light directly destroys microorganism.
Model(s)	Model 16108	QTZ300-60 and QTZ100-24
Installation	In-Duct	Free standing
Filter(s)	Pre-filter made with polyester and catalytic filter made with polyester and coated with titanium dioxide (TiO2)	Filter made with quartz fibers coated with titanium dioxide (TiO2)
Photocatalyst	Catalytic filter coated with TiO2 and metal wire mesh	Filter coated with TiO2
Light source	UV-A lamps (~320-400 nm)	UV-C Xenon Flash lamps (~100-285nm)

Element of Comparison	Transformair	ABRACAIR (K052732)
Voltage	Up to 120 Volt / 220 Volt (plugs into standard outlet) (See Footnote [1])	240 Volt AC / 480 Volt AC
Current	Up to 1.25 amps (See Footnote [1])	30 Amps at 240 Volts
Power Consumption	Up to 240 Watts (See Footnote [1]) and Footnote [2])	Up to 7020 Watts
Air cleaning chamber	Particulate pre-filter, UV-A lamps and a catalytic filter coated with TiO2 and metal wire mesh	UV-C lamps and a catalytic filter coated with TiO2
Electronics	UL compliant	UL compliant
Dimensions	28.5 inches by 21 inches by 12.25 inches	Not available

[1] This does not raise any new issues of safety and efficacy since the Transformair Air Purifier complies with the applicable UL standards for an air duct mounted device.

[2] Transformair Air Purifier is different from the primary predicate device since it uses upto 240 W of UV-A light (320-400 nm) with a TiO_2 coated catalytic filter and a metal wire mesh to enhance activation of the TiO_2 photocatalyst instead of upto 7020 W of UV-C light (~100-285nm) used by the primary predicate. This does not raise any new issues of efficacy since the ability of the Transformair device to reduce the concentration of airborne microorganisms is substantiated by the performance testing.

The Transformair Air Purifier and the predicate ABRACAIR Air Cleaners use the action of UV light on a catalytic filter coated with a Titanium Oxide (TiO2) photocatalyst to destroy microbiological contaminants in the air. Both devices use conventional UV-light lamps and filter materials but, unlike the predicate, the Transformair Air Purifier uses UV-A lamps instead of UV-C lamps and has a metal wire mesh on the catalytic filter. Both devices are designed to operate in a medical facility.

The Transformair air purifier has the same intended use of reducing airborne bacteria and mold spores as the predicate device ABRACAIR Air Cleaner (K052732). In addition, the Transformair air purifier is intended to reduce viruses (MS2 and Phi-X174).

The differences in the indications for use and technological characteristics are supported by the performance testing and UL electrical safety testing and do not raise new questions of safety or efficacy.

Non-Clinical Performance Testing Summary:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the Transformair Air Purifier has been tested to demonstrate that the device does not generate Ozone. It has also been certified compliant with the following UL standards:

- ANSI/UL 1995-2011 & CAN-CSA C22.2 No. 236-11, Heating and Cooling Equipment and
- UL 2043, Heat and Visible Smoke Release For Discrete Products and Their Accessories Installed in Air-Handling Spaces.

Reference the Table below for specific UL tests conducted.

Table 4: Underwriters Laboratories Testing Summary

Test Conducted	UL Reference Standard	Test Results
Input Test (Circuits – Other than Electric Heaters) (+)	UL 1995, 4th Ed., Section 40	PASS
Starting Test	UL 1995, 4th ed. Section 69	PASS
Leakage Current Test	UL 1995, 4th ed. Section 68	PASS
Temperature Operation Test (Without Any Supplementary Heating Means)(+)	UL 1995, 4th Ed., Section 41	PASS
Dielectric Voltage-Withstand Test	UL 1995, 4th Ed., Section 54	PASS
Fire Test for Heat and Visible Smoke Release For Discrete Products and Their Accessories Installed in Air-Handling Spaces	UL 1995, 4th Ed., Section 18 and UL 2043, 3rd Ed.	PASS

Third party testing was also performed to evaluate filter performance using aerosolized suspensions of the claimed microorganisms. This testing demonstrated retention of the test organisms on the filter. This testing was done in compliance with FDA Good Laboratory Practices (GLP) as defined in 40 CFR, Part 160.

Lastly, third party testing was performed to establish the kill kinetics for bacteria (Staphylococcus epidermidis and Escherichia coli), viruses (MS2 and Phi-X174), and mold spores (Aspergillus Niger) and bacterial spores (Bacillus globigii) over the range of temperatures expected to occur in an HVAC duct. This testing was done in compliance with FDA Good Laboratory Practices (GLP) as defined in 40 CFR, Part 160. Reference Table below for the lethality testing results.

Table 5: Transformair Device Lethality Testing Results

Category	Aerosolized Biological	Test Temperature (°F)	Exposure time (hours)	Average Maximum log reduction
Bacteria	**Staphylococcus epidermidis**	45°F	24 hours	4.88
		72°F	0.33 hour	4.02
		110°F	0.33 hour	4.20
Bacteria	**Escherichia coli**	45°F	24 hours	4.31
		72°F	24 hours	4.79
		110°F	0.33 hour	4.40
Virus	**MS2 bacteriophage**	45°F	24 hours	4.13
		72°F	24 hours	4.25
		110°F	24 hours	5.51
Virus	**Phi-X174 bacteriophage**	45°F	24 hours	4.37
		72°F	24 hours	4.37
		110°F	24 hours	4.37
Mold spore	**Aspergillus Niger spores**	45°F	72 hours	3.91
		72°F	72 hours	3.99
		110°F	72 hours	4.22
Bacterial spore	**Bacillus globigii spores**	45°F	72 hours	4.11
		72°F	72 hours	4.41

		110°F	72 hours	4.41

Clinical Testing Summary:

Clinical testing has not been performed for the Transformair Air Purifier. Non-clinical bench testing is sufficient to demonstrate substantial equivalence to the predicate ABRACAIR Air Cleaner.

Conclusion:

The subject device is substantially equivalent to the predicate device.