

K 033448

JUL 1 2 2004

### 510(k) SUMMARY

#### Air Purifier 3707 UVC

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510Kk) Summary.

1. **Submitted By:**

Dr. John Yuen  
John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA  
A GROUP  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Tel: 1-626-581-1290      Fax: 1-626-581-1291  
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

**Date Revised:**

April 02, 2004  
June 2, 2004

4. **Proprietary Name:**

**Air Purifier 3707 UVC**

5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

AiroCide TiO2 (K023830)

8. **Device Description**

**Air Purifier 3707 UVC** device is an adjustable and portable personal system for treating air in a specified area of a room. **Air Purifier 3707 UVC** device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path. **Air Purifier 3707 UVC** device contains also an air filtering system with an Ultraviolet radiation tube which purified air.

9. **Intended Use:**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

10. **Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Air Purifier 3707 UVC** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

11. Substantial Equivalence:

The **Air Purifier 3707 UVC** is substantial equivalence to **AiroCide TiO2 (K023830)** in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

510(k) Summary for Use



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**

**Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850**

**JUL 1 2 2004**

John Manufacturing Limited  
C/O Mr. Arthur King Ma  
A GROUP, Incorporated  
18780 Amar Road Suite 202-203  
Walnut, California 91789

Re: K033448  
Trade/Device Name: Air Purifier 3707 UVC  
Regulation Number: 880.6500  
Regulation Name: Medical Ultraviolet Air Purifier  
Regulatory Class: II  
Product Code: FRA, FRF  
Dated: June 29, 2004  
Received: June 29, 2004

Dear Mr. King Ma:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. King Ma

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

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 (if known): K033448

Device Name: **Air Purifier 3707 UVC**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Maehy  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
510(k) Number: K033448

K 033448/A'

July 1, 2004

To: Ms. Feli A. Marshall, Nurse Consultant, INCB, DAGID  
Phone No.: 301-443-8913 Fax No. 301-480-3002  
RE: K033448 Total page: 03

Dear Ms. Feli Marshall:

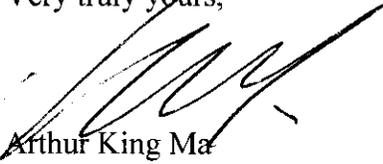
Regarding the above application, kindly refer the following below in connection to our telephone conversation:

1. We have deleted the claim that the subject device can remove and/or reduce bacteria in the air from the indication of use.
2. Moreover, we have deleted claim that the subject device can remove and/or reduce bacteria in the air from its packaging.
3. Please refer the fax for our proposed packaging.

Please give the undersigned a call at or 626-786-0075 should there is any other concerns or questions that you might encountered.

I thank you very much for your kind attention in this matter and look forward for your approval for the subject device.

Very truly yours,



Arthur King Ma  
For and on behalf of  
John Manufacturing Ltd.

P.S. Please let me know if I need to submit any additional information therefore, I can mail the originals to you.

FDX/CDRH/EE/PI  
2004 JUL -1 A 11:01  
RECEIVED

SK 11

22

**Indications for Use**

510(k) Number (if known): K033448

Device Name: **Air Purifier 3707 UVC**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

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(21 CFR 807 Subpart C)

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---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Proposed Packaging:

Air Purifier 3707 UVC

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

US Sole Agent:

A GROUP  
18780 Amar Road, STE 203  
Walnut, CA 91789  
Customers Service No.: 626-581-1290

Manufacturer:

John Manufacturing Ltd.  
6/F., Yau Lee Center, 46 Hoi Yuen Rd.,  
Kwun Tong, Kowloon, Hong Kong

FOR EXPORT USE ONLY

READ INSTRUCTION OF USE AND CARE BEFORE USING.



July 1, 2004

To: Ms. Feli A. Marshall, Nurse Consultant, INCB, DAGID  
Phone No.: 301-443-8913 Fax No. 301-480-3002  
RE: K033448 Total page: 03

Dear Ms. Feli Marshall:

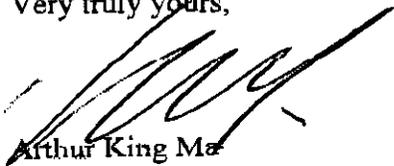
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July 1, 2004

To: Ms. Feli A. Marshall, Nurse Consultant, INCB, DAGID  
Phone No.: 301-443-8913 Fax No. 301-480-3002  
RE: K033448 Total page: 02

Dear Ms. Feli Marshall:

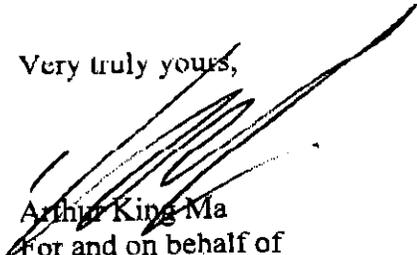
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Very truly yours,



Arthur King Ma  
For and on behalf of  
John Manufacturing Ltd.

P.S. Please let me know if I need to submit any additional information therefore, I can mail the originals to you.

**Indications for Use**

510(k) Number (if known): K033448

Device Name: **Air Purifier 3707 UVC**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**Air Purifier  
Model No. 3707 UVC**

**Proposed Packaging:**

The air purifier 3707 UVC is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

**US Sole Agent:**

A GROUP  
18780 Amar Road, STE 203  
Walnut, CA 91789  
Customers Service No.: 626-581-1290

**Manufacturer:**

John Manufacturing Ltd.  
6/F., Yau Lee Center, 46 Hoi Yuen Rd.,  
Kwun Tong, Kowloon, Hong Kong

FOR EXPORT USE ONLY



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**Installation and Operation**

No Installation is required. Just plug the unit into any standard electrical outlet and operate it by the switch.

**Placement**

Never place the unit on or near electronic devices that contain electronic circuits or any flammable gases such as oxygen or gas.

**Warnings:**

Do not use the unit with any extension cord.

Do not use the unit when hands are wet. You may get hurt from electric shock from water contact.

Do not operate the unit near any flammable gases or oxygen.

Do not operate the unit at any outdoor as it is designed for indoor use.

Do not block any opening of the unit.

Never let children to operate the unit.

Always unplug the unit before performing any maintenance.

Manufacturer: John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

Telephone: 852-2341-1228

Precaution when consumers want to clean and give the subject device a regular maintenance, the following steps are highly recommended:

1. It is recommended that an Adult User should provide routine service the unit every two weeks.
2. Remember to unplug the unit before any cleaning.
3. Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
4. Dust filler – Take off the dust filter and wash the dust filter using tap water. Allow it to dry completely before putting it back. Place the filter until it is property fitted. Never operate the unit without the filter in place. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
5. Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.
6. Since the UV lamp is disposable, UV lamp can be replaced when it is burns out. Please unplug the device with any input of electricity before charging the UV lamp. Wash the used UV lamp with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
7. Filter can be replaced as needed. 2 Extra filters are included with purchase. (Normally, it is advised to replace the filter every 6 month even with the regular cleaning in every 2 week to ensure the best results.) Please unplug the device with any inputs of electricity before charging the filter. Wash the used filter with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)

July 5, 2004

To: Ms. Feli A. Marshall, Nurse Consultant, INCB, DAGID  
Phone No.: 301-443-8913 Fax No. 301-480-3002  
RE: K033448 Total page: 10

Dear Ms. Feli Marshall:

Regarding the above application, kindly refer the following below in connection to our telephone conversation:

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2. Moreover, we have deleted claim that the subject device can remove and/or reduce bacteria in the air from its packaging.
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Very truly yours,

Arthur King Ma  
For and on behalf of  
John Manufacturing Ltd

P.S. Please let me know if I need to submit any additional information therefore, I can mail the originals to you.

**Indications for Use**

510(k) Number (if known): K033448

Device Name: **Air Purifier 3707 UVC**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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## **510(k) SUMMARY**

### **Air Purifier 3707 UVC**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510(k) Summary.

1. **Submitted By:**

Dr. John Yuen  
John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA  
A GROUP  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Tel: 1-626-581-1290      Fax: 1-626-581-1291  
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

**Date Revised:**

April 02, 2004

June 2, 2004

4. **Proprietary Name:**

Air Purifier 3707 UVC

5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

AiroCide TiO<sub>2</sub> (K023830)

8. **Device Description**

**Air Purifier 3707 UVC** device is an adjustable and portable personal system for treating air in a specified area of a room. **Air Purifier 3707 UVC** device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path. **Air Purifier 3707 UVC** device contains also an air filtering system with an Ultraviolet radiation tube which purified air.

**Air Purifier 3707 UVC** device employs Ultraviolet radiation tube to eliminate germs, viruses, fungi and airborne microorganisms or particles in the air. When air full of germs, viruses, fungi and other harmful airborne microorganisms or particles in the air moved into the device, ultraviolet radiation tube generates ultraviolet to eliminate germs, viruses, fungi and other harmful airborne microorganisms or particles in the air. Then purified air is emitted to exhaust frame.

9. **Intended Use:**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

10. **Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Air Purifier 3707 UVC** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

11. **Substantial Equivalence:**

The **Air Purifier 3707 UVC** is substantial equivalence to AiroCide TiO<sub>2</sub> (K023830) in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

Precaution when consumers want to clean and give the subject device a regular maintenance, the following steps are highly recommended:

1. It is recommended that an Adult User should provide routine service the unit every two weeks.
2. Remember to unplug the unit before any cleaning.
3. Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
4. Dust filler – Take off the dust filter and wash the dust filter using tap water. Allow it to dry completely before putting it back. Place the filter until it is properly fitted. Never operate the unit without the filter in place. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
5. Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.
6. Since the UV lamp is disposable, UV lamp can be replaced when it is burns out. Please unplug the device with any input of electricity before charging the UV lamp. Wash the used UV lamp with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
7. Filter can be replaced as needed. 2 Extra filters are included with purchase. (Normally, it is advised to replace the filter every 6 month even with the regular cleaning in every 2 week to ensure the best results.) Please unplug the device with any inputs of electricity before charging the filter. Wash the used filter with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the

ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)

### Table of Comparisons

Predicate Device	Proposed Device
AiroCide TiO2 (K023830)	Air Purifier 3707 UVC
Classification Name: <b>Medical Ultraviolet Air Purifier</b>	Classification Name: <b>Medical Ultraviolet Air Purifier</b>
Classification: <b>Class II</b> Product Code: <b>FRA</b>	Classification: <b>Class II</b> Product Code: <b>FRA</b>
Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>	Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>
Indication for Use: <b>Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.</b>	Indication for Use: <b>The air purifier 3707 UVC is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.</b>
Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet treated air outlet, a blower, a filter, a heater and humidifier.</b>	Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet, treated air outlet, a blower, a filter, an Ultraviolet radiation tube.</b>
Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.</b>	Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the Electro-Optical Air Sterilizer with Ionizer device complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2</b>

	No. 187-M1986.
Conclusion: The AiroCide TiO2 device is the predicate device to the proposed device, namely, the Air Purifier 3707 UVC device due to their substantially equivalent features.	Conclusion: The Air Purifier 3707 UVC device is substantially equivalent to the AiroCide TiO2 device due to the substantially equivalent features.

### Instruction of Use

Air Purifier  
Model No. 3707 UVC

#### Installation and Operation

No Installation is required. Just plug the unit into any standard electrical outlet and operate it by the switch.

#### Placement

Never place the unit on or near electronic devices that contain electronic circuits or any flammable gases such as oxygen or gas.

### Warnings:

- Do not use the unit with any extension cord.
- Do not use the unit when hands are wet. You may get hurt from electric shock from water contact.
- Do not operate the unit near any flammable gases or oxygen.
- Do not operate the unit at any outdoor as it is designed for indoor use.
- Do not block any opening of the unit.
- Never let children to operate the unit.
- Always unplug the unit before performing any maintenance.

Manufacturer: John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China  
Telephone: 852-2341-1228

38

•  
USA Contact: A GROUP Incorporated  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Telephone 626-581-1290



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUL 1 2 2004**

John Manufacturing Limited  
C/O Mr. Arthur King Ma  
A GROUP, Incorporated  
18780 Amar Road Suite 202-203  
Walnut, California 91789

Re: K033448  
Trade/Device Name: Air Purifier 3707 UVC  
Regulation Number: 880.6500  
Regulation Name: Medical Ultraviolet Air Purifier  
Regulatory Class: II  
Product Code: FRA, FRF  
Dated: June 29, 2004  
Received: June 29, 2004

Dear Mr. King Ma:

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.

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Page 2 – Mr. King Ma

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This letter will allow you to begin marketing your device as described in your Section 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.

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Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2

**Indications for Use**

510(k) Number (if known): K033448

Device Name: **Air Purifier 3707 UVC**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEED**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Mueley  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
510(k) Number: K033448

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

May 12, 2004

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

JOHN MFG., LTD.  
C/O A GROUP  
18780 AMAR ROAD, STE 203-203  
WALNUT, CA 91789  
ATTN: ARTHUR KING MA

510(k) Number: K033448  
Product: ELECTRO-OPTICAL  
AIR STERILIZER  
WITH IONIZER

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

les

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

February 02, 2004

JOHN MFG., LTD.  
C/O A GROUP  
18780 AMAR ROAD, STE 203-203  
WALNUT, CA 91789  
ATTN: ARTHUR KING MA

510(k) Number: K033448  
Product: ELECTRO-OPTICAL  
AIR STERILIZER  
WITH IONIZER

Extended Until: 05-APR-2004

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

**A Group Realty & Investment, Inc.**

18780 Amar Road, Suite 202-203, Walnut, CA 91789  
Tel.: (626) 581-1290 Fax. (626) 581-1291

January 26, 2004

Feli A. Marshall, Nurse Consultant, INCB, DAGID (HFZ-480)  
Food and Drug Administration  
Center for Device and Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Rockville, Maryland 20850

RECEIVED  
2004 FEB -2 P. 3: 04  
FOIA/AM/01/002/9110

VIA FACSIMILE at 1-301-480-3002  
VIA First Class Mail to both (HFZ-401 & HFZ-408)

RE: Extension Requested fro 501(K) Number: K03448

*K 033448*

Dear Feli A. Marshall:

Relative to the above, please accept our request for extension on preparing our reply and provide to you with the additional information.

We are in the process of conducting numbers of tests with a laboratory; namely, (b)(4) and results from those tests will be used to answer some of the critical questions proposed by you in relation to our application.

Since the busy schedule of the laboratory and the time needed for assembling the necessary cabinets, the first available schedule given to us will be on the third week of February, 2004, therefore, please grant us a 45 days extension from February 05, 2004.

We appreciate it very much for your kindness attention in this matter and should there is anything else needed, please give the undersigned a call.

Thank you very kindly for you attention and approval for our request.

Very truly you,

  
Arthur King Ma

*SK 48*

**A Group Realty & Investment, Inc.**

18780 Amar Road, Suite 202-203, Walnut, CA 91789  
Tel.: (626) 581-1290 Fax. (626) 581-1291

January 26, 2004

Feli A. Marshall, Nurse Consultant, INCB, DAGID (HFZ-480)  
Food and Drug Administration  
Center for Device and Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Rockville, Maryland 20850

VIA FACSIMILE at 1-301-480-3002  
VIA First Class Mail to both (HFZ-401 & HFZ-408)

*K033448*

RE: Extension Requested fro 501(K) Number: K03448 

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Relative to the above, please accept our request for extension on preparing our reply and provide to you with the additional information.

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Thank you very kindly for you attention and approval for our request.

Very truly you,

  
Arthur King Ma

*JK-49*

FDA/CDRH/OC/ED/110  
2004 FEB -5 P 4: 59

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

January 06, 2004

JOHN MFG., LTD.  
C/O A GROUP  
18780 AMAR ROAD, STE 203-203  
WALNUT, CA 91789  
ATTN: ARTHUR KING MA

510(k) Number: K033448  
Product: ELECTRO-OPTICAL  
AIR STERILIZER  
WITH IONIZER

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

November 05, 2003

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

JOHN MFG., LTD.  
C/O A GROUP  
18780 AMAR ROAD, STE 203-203  
WALNUT, CA 91789  
ATTN: ARTHUR KING MA

510(k) Number: K033448  
Received: 03-NOV-2003  
Product: ELECTRO-OPTICAL AIR  
STERILIZER WITH  
IONIZER

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Office of Device Evaluation  
Center for Devices and Radiological Health

135

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
 Center for Devices and  
 Radiological Health  
 Office of Device Evaluation  
 Document Mail Center (HFZ-401)  
 9200 Corporate Blvd.  
 Rockville, Maryland 20850

October 30, 2003

JOHN MFG., LTD.  
 C/O A GROUP  
 18780 AMAR ROAD, STE 203-203  
 WALNUT, CA 91789  
 ATTN: ARTHUR KING MA

510(k) Number: K033448  
 Received: 29-OCT-2003  
 Product: ELECTRO-OPTICAL AIR  
 User Fee ID Number: 11732 WITH  
 IONIZER

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

## By Regular Mail

-----  
 Food and Drug Administration  
 P.O. Box 956733  
 St. Louis, MO 63195-6733.

## By Private Courier (e.g., Fed Ex, UPS, etc.)

-----  
 U.S. Bank  
 956733  
 1005 Convention Plaza  
 St. Louis, MO 63101  
 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

033448

**A Group, Inc.**

18780 Amar Road, Suite 202-203, Walnut, CA 91789  
Tel.: (626) 581-1290 Fax. (626) 581-1291

October 27, 2003

Food and Drug Administration  
Center for Devices and Radiological Health  
510(k) Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

Major Resource Documents

To Whom It May Concern:

RE: FDA 510(k) Premarket Notification Submission for Electro-Optical Air Sterilizer  
with Ionizer

2003 OCT 29 PM 2:32

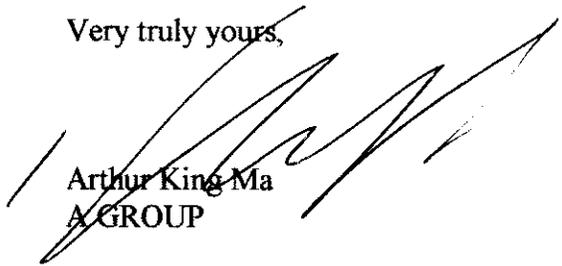
Relative to the above, please see the enclosed package containing the following items:

1. Two copies of Premarket Notification
2. A copy of medical device user fee cover sheet with the Identification Number:  
(b)(4)

Please process this submission and inform the undersigned accordingly.

Thank you very kindly for your attention in this matter.

Very truly yours,



Arthur King Ma  
A GROUP

H0 II

51231

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4)
	Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)  A GROUP, INC. 18780 AMAR ROAD, STE 202-203 WALNUT, CA 91789	2. CONTACT NAME ARTHUR MA
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 061638912	2.1 E-MAIL ADDRESS am@agroup.org
	2.2 TELEPHONE NUMBER (Include Area Code) 626-581-1290
	2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 626-581-1291

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

<p>Select an application type:</p> <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)	<p>3.1 Select one of the types below:</p> <input checked="" type="checkbox"/> Original Application <p>Supplement Types:</p> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
---	--

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA  NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:  
SBD-04-

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES  NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b)(4)

Form FDA 3601 (08/2003)

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<b>510(k) SUMMARY</b>	<b>14</b>
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<b>Exhibit A</b> <b>4 Drawings for Proposed Devices</b>	<b>Totaling 04 pages</b>
<b>Exhibit B</b> <b>A Completed Report prepared by UL</b>	<b>Totaling 15 pages</b>
<b>Exhibit C</b> <b>A Completed Summary for Predicate Device</b> <b>THE BREATHE EAST (K981841)</b>	<b>Totaling 05 pages</b>
<b>Exhibit D</b> <b>A Copy of Actual Proposed User Manual</b>	<b>Totaling 04 pages</b>
<b>Exhibit E</b> <b>A Copy of Actual Proposed Packaging</b>	















## **Information on Sterilization**

The proposed Electro-Optical Air Sterilizer with Ionizer device required no special sterilization due to its built-in Ultraviolet radiation tube, which emits ultraviolet radiations to destroy germs, remove airborne particles all allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites, and harmful fibers, that may lead to allergic reactions.

However, should an end-user wants to clean and give the proposed device a regular maintenance, the following steps are highly recommended:

1. It is recommended to routine service the unit every two weeks.
2. Remember to unplug the unit before any cleaning.
3. Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
4. Use a soft brush to lean the carbon fiber on the front outlet grill.
5. Dust filler – Take off the dust filter and wash it by tap water. Allow it to dry completely before putting it back. Place the filter until it is property fitted. Never operate the unit without the filter in place.
6. Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.

**(The forgoing maintenance information was printed in the user manual.)**

Table of Comparisons

Predicate Device	Proposed Device
Breathe Easy (RespirAid Ltd.) K981841	Electro-Optical Air Sterilizer with Ionizer
Classification Name: <b>Medical Recirculating Air Cleaner</b>	Classification Name: <b>Medical Recirculating Air Cleaner</b>
Classification: <b>Class II</b> Product Code: <b>FRF</b>	Classification: <b>Class II</b> Product Code: <b>FRF</b>
Regulation No.: <b>880.5045</b> Reviewed By: <b>General Hospital Devices</b>	Regulation No.: <b>880.5045</b> Reviewed By: <b>General Hospital Devices</b>
Indication for Use: <b>The Breathe Easy device is a medical Recirculating air cleaner designed to remove airborne particles and allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites, and harmful fibers, that may lead to allergic reactions.</b>	Indication for Use: <b>The Electro-Optical Air Sterilizer with Ionizer device is a medical Recirculating air cleaner designed to remove airborne particles all allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites, and harmful fibers, that may lead to allergic reactions.</b>
Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit,, an air inlet treated air outlet, a blower, a filter, a heater and humidifier.</b>	Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet, treated air outlet, a blower, a filter, an Ultraviolet radiation tube and a high negative voltage carbonated fiber.</b>
Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the BREATHE EASY complies with the IEC 601-1.</b>	Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the Electro-Optical Air Sterilizer with Ionizer device complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.</b>
Conclusion: <b>The BREATHE EASY device is the predicate device to the proposed device, namely, the Electro-Optical Air Sterilizer with Ionizer device due to their substantially equivalent features.</b>	Conclusion: <b>The Electro-Optical Air Sterilizer with Ionizer device is substantially equivalent to the BREATHE EASY device due to the substantially equivalent features.</b>

Record processed under FOIA/Kennedy-Kuznetsov Act. Released by CDRH on 03-07-2016.

K 033448

**sterilizing Function:**

germicidal UV-C emitting short-wave violet radiation for destroying

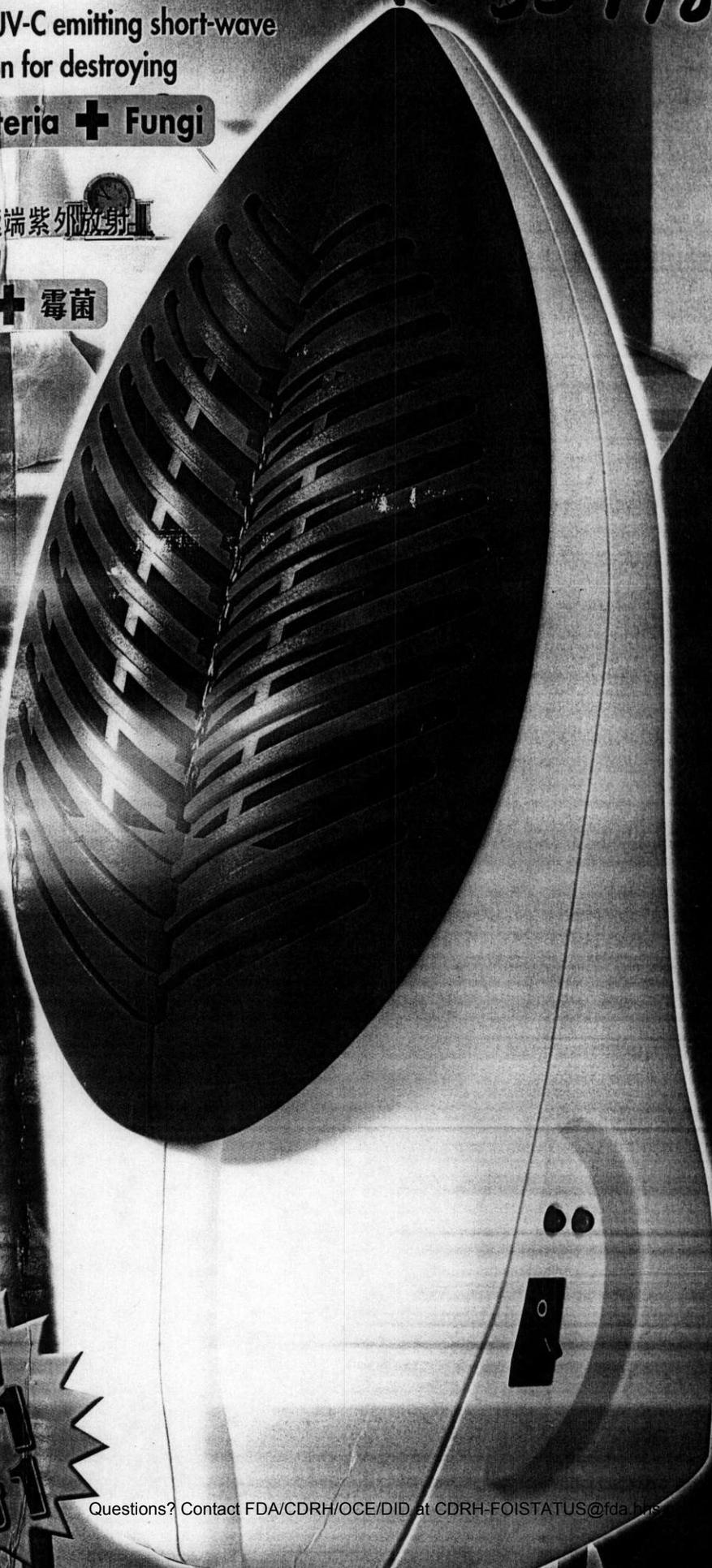
**Viruses + Bacteria + Fungi**

消毒作用：

UV-C 產生極端紫外放射

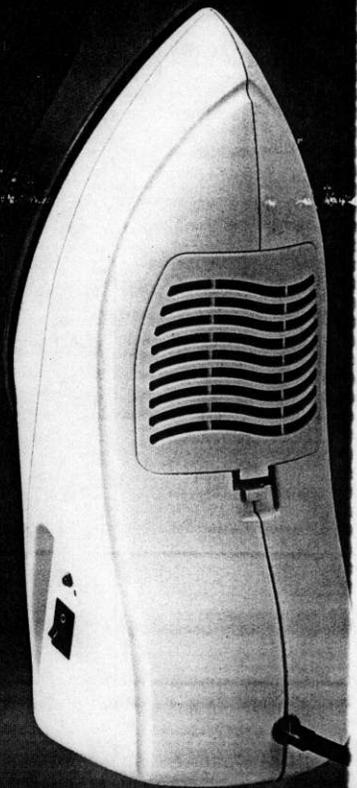
殺滅空氣中的

**病毒 + 細菌 + 霉菌**



**3-step air purification:**

1. Surrounding air drawn into Air Sterilizer.
2. Short-wave UV rays kill virus, bacteria and fungi.
3. Purified air driven out for your breathing.



**NEW 2 IN 1 2合1**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov

Note  
The UV-C radiation output of these lamps is indicated by the following warning sign.



Radiation of these lamps is harmful to eyes and skin.



祖科

祖科

Records processed under FOIA Request #2017-0366, Released by CDRH on 03-07-2016

nizer

空氣淨化器

n virus carriers  
haled by users

ns. More sophisticated  
infectious viruses have  
ht through these filters,  
ermination.

起  
毒  
放心

優良的口罩能過濾小至

罩所能過濾。

的極端紫外放射光線也  
殺滅。

ng the air.  
mountaintops.  
, greasy cooking smoke,  
ur, pollen etc.

ovel Design  
n

karaoke, banks, libraries,  
ses, and other residential  
environment.

菌、殺蟲劑殘留、寵物軟

# Air Sterilizer with Ionizer

## 祖科光電子殺菌殺病毒 兼離子空氣淨化器

# K 033448

**Sterilizing Function:**

Using germicidal UV-C emitting short-wave  
ultraviolet radiation for destroying

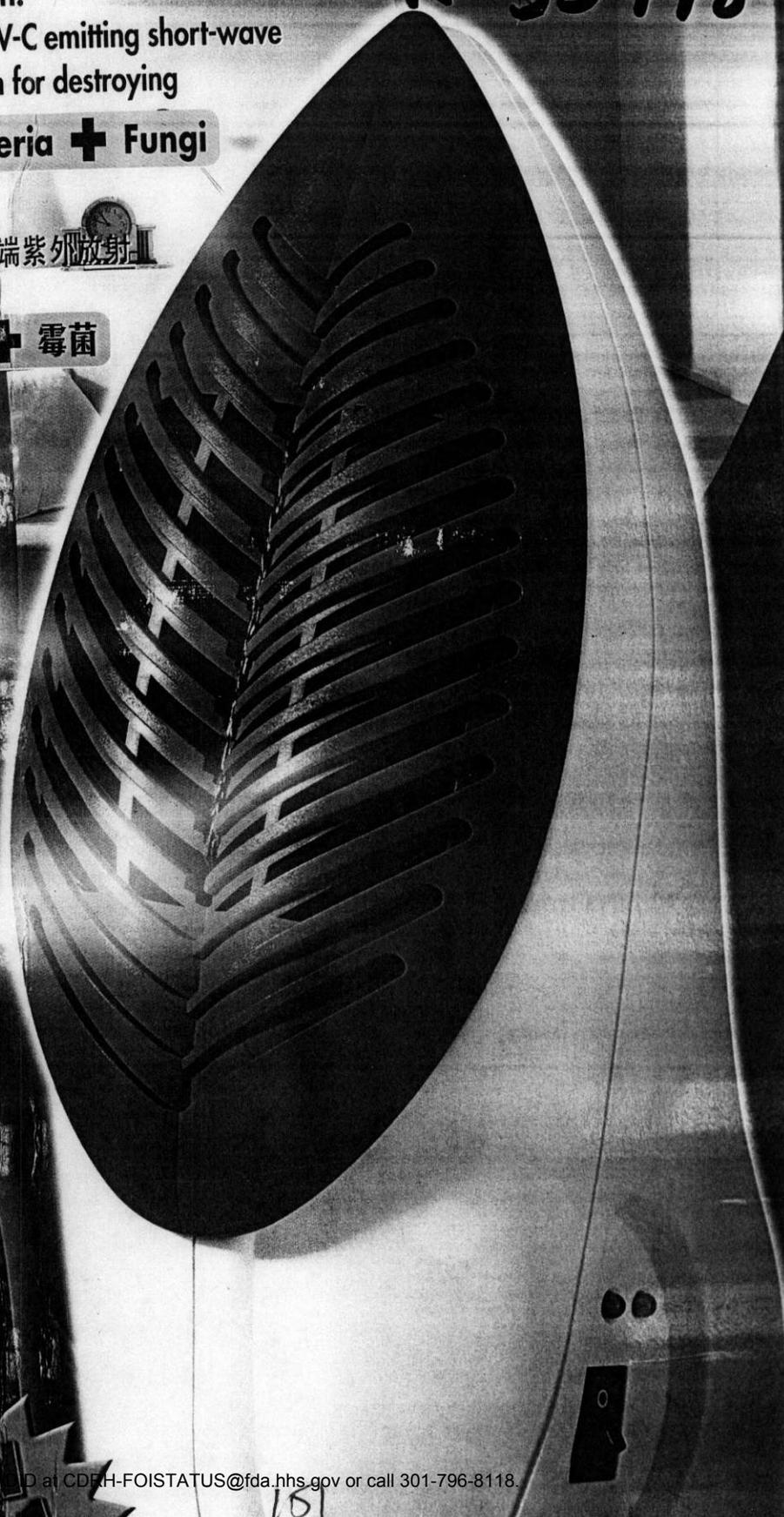
**Virus + Bacteria + Fungi**

殺菌消毒作用：

採用 UV-C 產生極端紫外放射

光線殺滅空氣中的

**病毒 + 細菌 + 霉菌**



Questions? Contact FDA at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

**NEW**

151

# Sterilizing the exhaled air from virus carriers Improving the quality of air inhaled by user

Ordinary masks filter particles down to 3 microns. More sophisticated masks may go further to 0.3 micron. Many infectious viruses have diameters less than 0.1 micron. They go right through these filters but cannot escape the Ultra-Violet rays extermination.

**病毒細菌及時清除 健康生活由此起  
將帶菌者呼出的混濁空氣 殺菌消毒  
讓使用者 享受到清新空氣 健康放心**

一般口罩只能過濾3微米以上的物體，較優良的口罩能過濾小至0.3微米的物體。

但很多傳染性病毒直徑小於0.1微米，非一般口罩所能過濾。

令人鼓舞的是：病毒體積再小，本機的極端紫外放射光線也能有效地將之清除，更可一併把細菌殺滅。

### Ionizing Function:

- Ionizer produces negative ions revitalizing the air.
- Giving you sensation of seaccasts and mountaintops.
- Removing pollutants like tobacco smoke, greasy cooking smoke, airborne bacteria, insecticide dust, pet fur, pollen etc.

### Advanced Technology Novel Design Simple Operation

For lifts, hospitals, clinics, schools, hotels, karaokes, banks, libraries, restaurants, video game centers, club houses, and other residential, commercial, industrial, and small indoor environment.

### 空氣淨化作用：

- 高科技負離子令空氣更具活力
- 給你海邊垂釣、山頂遠眺的相同感受
- 無論是二手煙、煮食油煙、浮游細菌或霉菌、殺蟲劑殘留、寵物毛、花粉，一切一切都一掃而空。

### 創新科技 設計獨特 操作簡便

適用於：升降機內、醫院、診所、學校課室、酒店房間、卡拉OK、銀行、圖書館、餐廳酒樓、遊戲機中心、網吧、會所、住宅、辦公室、其他室內環境

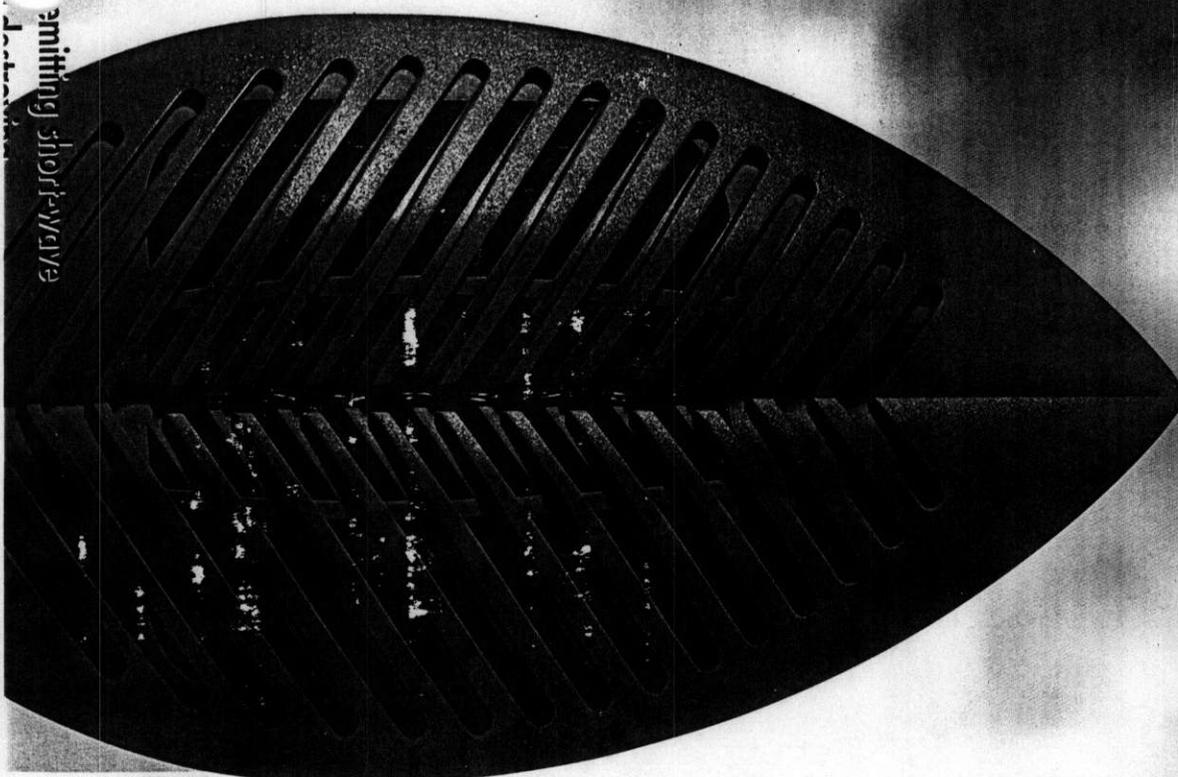
152

Ultra-Optical

祖科

Sterilizer with Ionizer

光電子殺菌殺病毒 兼離子空氣淨化器



g Function:  
micidal U  
emitting shorts waves

Ultra-Optical

祖科

Air Sterilizer with Ionizer

祖科光電子殺菌殺病毒 兼離子空氣淨化器

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**Ionizing Function:**

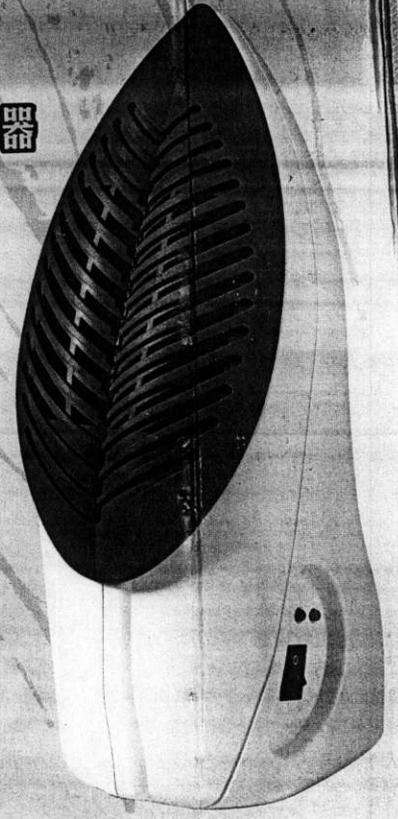
- Ionizer produces negative ions revitalizing the air.
- Giving you sensation of sea-breeze and mountain-tops.
- Removing pollutants like tobacco smoke, greasy cooking smoke, airborne bacteria, insecticide dust, pet fur, pollen etc

103

# Electro-Optical Air Sterilizer with Ionizer

祖科光電子殺菌殺病毒 兼離子空氣淨化器

**NEW  
2 IN 1  
2合1**



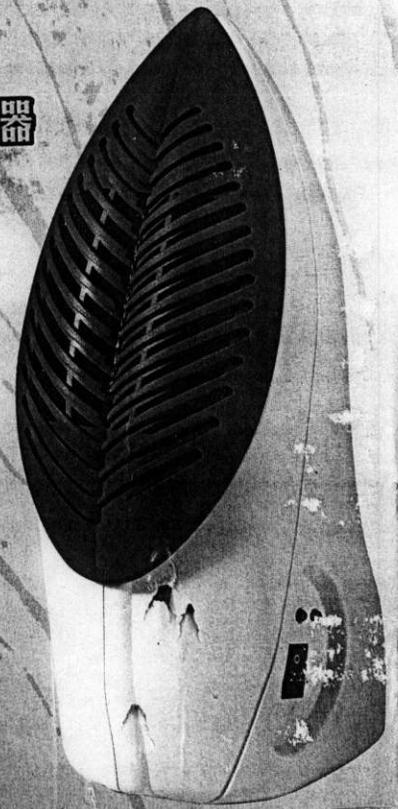
Operating voltage: 工作電壓:  
220V-240V 50 Hz

JML3707UVC

# Electro-Optical Air Sterilizer with Ionizer

祖科光電子殺菌殺病毒 兼離子空氣淨化器

**NEW  
2 IN 1  
2合1**



154

# Electro-Optical



祖科

## Air Sterilizer with Ionizer

### 祖科光電子殺菌殺病毒兼離子空氣淨化器

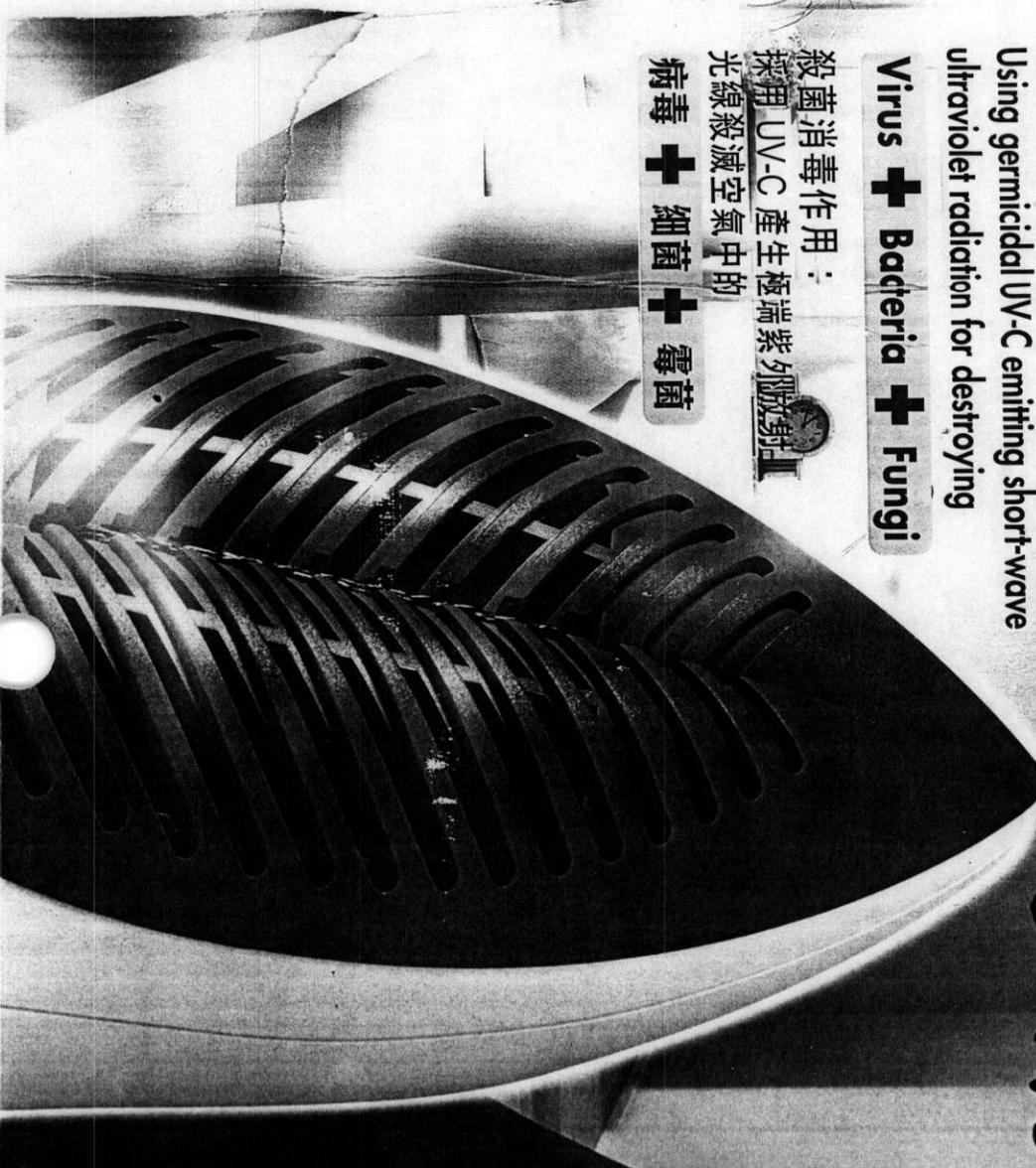
# K033448

**Sterilizing Function:**

Using germicidal UV-C emitting short-wave  
ultraviolet radiation for destroying

**Virus + Bacteria + Fungi**

殺菌消毒作用：  
採用 UV-C 產生極端紫外線  
光線殺滅空氣中的  
病毒 + 細菌 + 霉菌



# Electro-Optical

## Air Sterilizer

### 祖科光電子殺菌殺病毒

**3-step air purification:**

1. Surrounding air drawn in Air Sterilizer.
2. Short-wave UV rays kill virus, bacteria and fungi
3. Purified air driven out for your breathing.

# Electro-Optical



祖科

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K 033448

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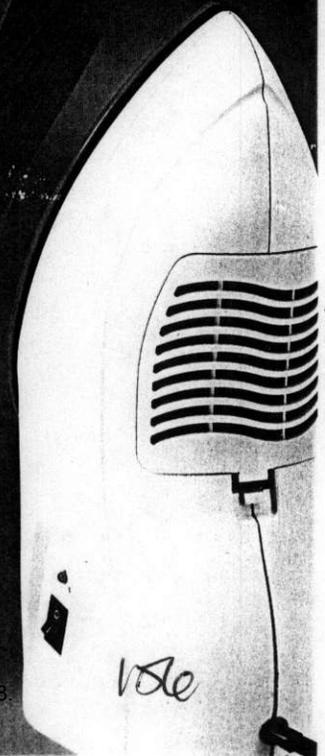
**病毒 + 細菌 + 霉菌**



# Electro-Optical Air Sterilizer 祖科光電子殺

### 3-step air purification

1. Surrounding air enters the Air Sterilizer.
2. Short-wave UV ray kills virus, bacteria and fungi.
3. Purified air driven into your breathing.



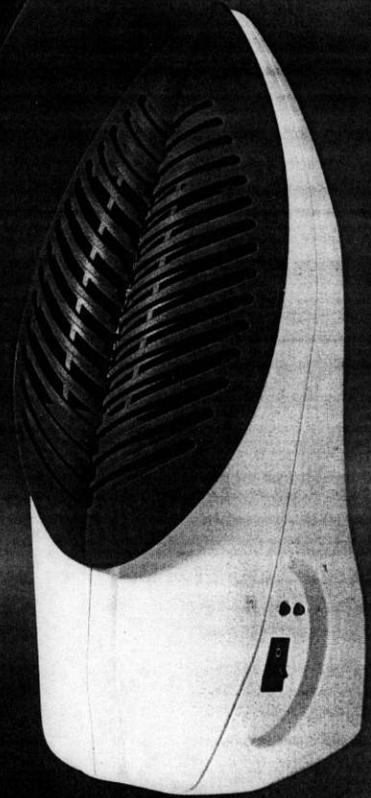
108e

# Air Sterilizer with Ionizer

## 祖科光電子殺菌殺病毒 兼離子空氣淨化器

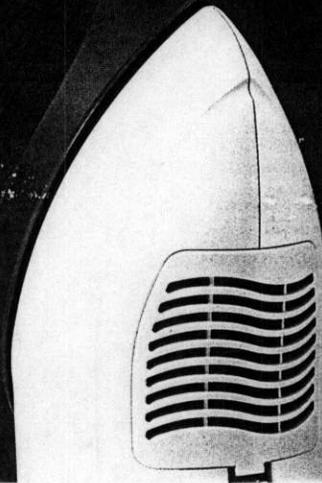
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1. Surrounding air drawn in Air Sterilizer.
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### 殺病毒、細菌、霉菌三步曲：

1. 機內抽風系統把室內空氣吸入
2. 極端紫外放射光線隨即殺滅病毒、細菌和霉菌
3. 消毒殺菌後的空氣再被送回室內



**Electro-Optical Air Sterilizer with Ionizer**  
 祖科光電子殺菌殺病毒 兼離子空氣淨化器

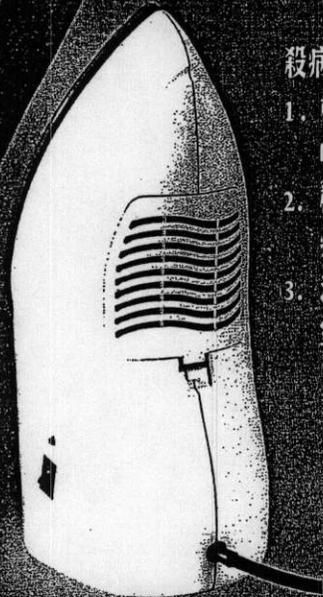


**Electro-Optical Air Sterilizer with Ionizer**  
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**IMPORTANT**  
 DO NOT DISASSEMBLE THE UNIT OR TAMPER WITH THE INTERIOR PARTS OF THE PRODUCT. ALWAYS REMEMBER TO UNPLUG THE UNIT BEFORE ANY CLEANING.

請勿拆卸機身或以任何方法修理內  
 部零件，否則可能引起危險。請在  
 清潔前，先將電源線拔去。

中國總經銷：祖科光電有限公司  
 中國總經銷：祖科光電有限公司

UK USA HKG  
 PATENTED & DES. PAT.



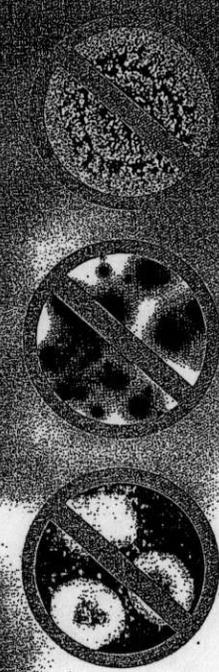
NOTE  
 The UV-C radiator output of these lamps is poisonous to the following warning sign.



Fluoride of these lamps is harmful to eyes and skin. Installation with these lamps are to be screened off completely.



6 73341 08153 1



**Sterilizing Function:**  
 Using germicidal UV-C emitting short-wave ultraviolet radiation for destroying  
**Virus + Bacteria + Fungi**

殺菌消毒作用  
 採用 UV-C 產生極端紫外放射  
 光線殺滅空氣中的  
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# Electro-Optical Air Sterilizer with Ionizer

祖科光電子殺菌殺病毒兼離子空氣淨化器



# Electro-Optical Air Sterilizer with Ionizer

祖科光電子殺菌殺病毒兼離子空氣淨化器



**Sterilizing the exhaled air from virus carriers  
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Ordinary masks filter particles down to 3 microns. More sophisticated masks may go further to 0.3 micron. Many infectious viruses have diameters less than 0.1 micron. They go right through these filters, but cannot escape the Ultra-Violet rays extermination.

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**Ionizing Function:**  
 ■ Ionizer produces negative ions revitalizing the air  
 ■ Giving you sensation of seacoasts and mountain tops  
 ■ Removing pollutants like tobacco smoke, greasy cooking smoke, airborne bacteria, insecticide dust, hair, pollen, etc.

Advanced Technology Novel Design  
Simple Operation

For lifts, hospitals, clinics, schools, hotels, karaoke rooms, bars, restaurants, video game centers, club houses, and other residential, commercial, industrial, and small indoor environment.

**空氣淨化作用：**  
 ■ 高科技負離子令空氣更具活力  
 ■ 給你海邊垂釣、山頂遠眺的相同感受  
 ■ 無論是二手煙、煮食油煙、浮游細菌或霉菌、殺菌劑殘留、寵物皮毛、花粉，一切一切都一掃而空。

創新科技 設計獨特 操作簡便

適用於：升降機內、醫院、診所、學校課室、酒店房間、卡拉OK、銀行、圖書館、餐廳酒樓、遊戲機中心、網吧、會所、住宅、辦公室及其他室內環境。

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Using germicidal UV-C emitting short-wave ultraviolet radiation for destroying

Virus + Bacteria + Fungi

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採用UV-C產生極端紫外放射光線殺滅空氣中的

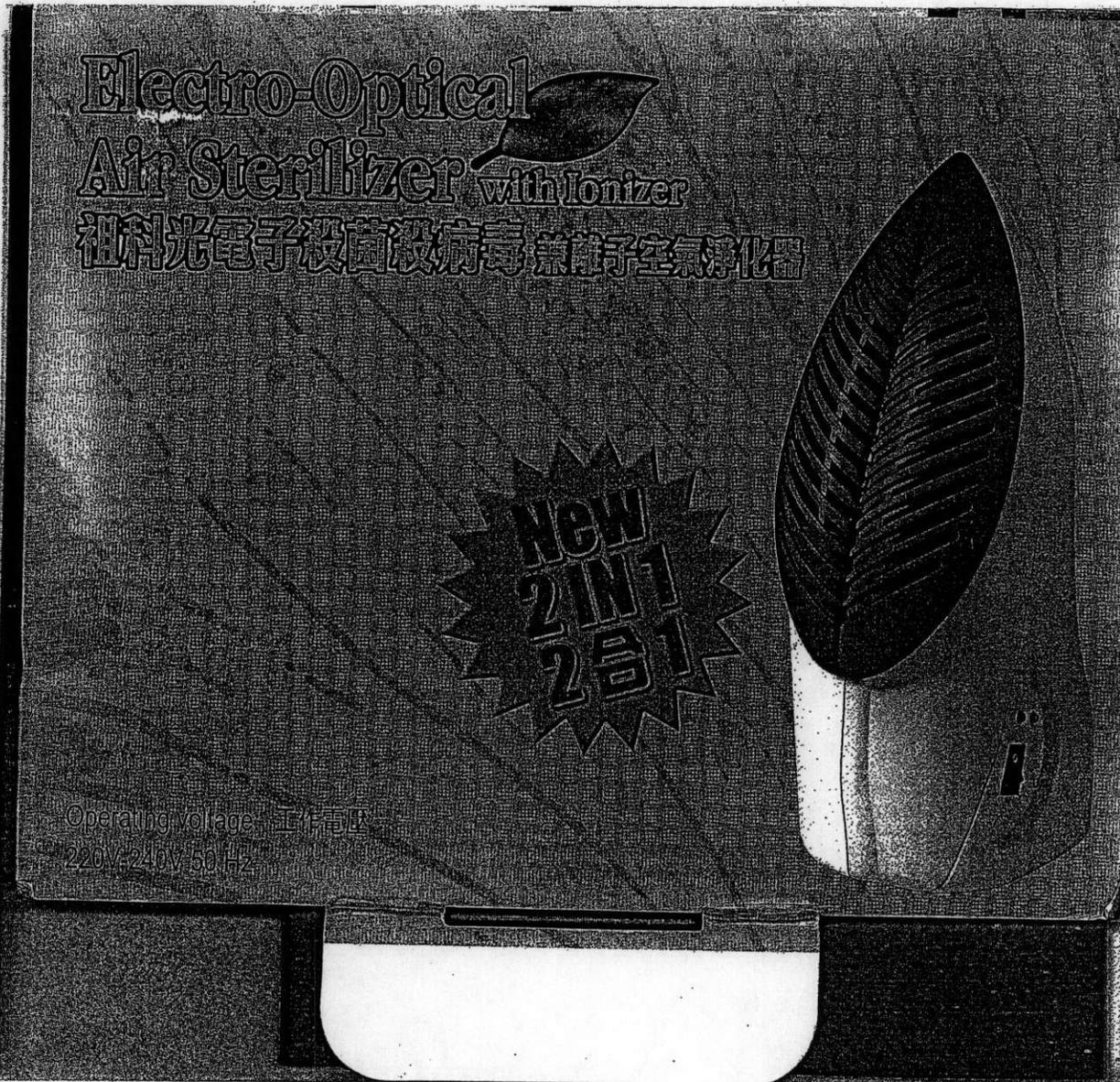
病毒 + 細菌 + 霉菌



**Proposed Package for The Electro-Optical Air Sterilizer with Ionizer device**



Proposed Package for The Electro-Optical Air Sterilizer with Ionizer device



# Proposed User's Manual for The Electro-Optical Air Sterilizer with Ionizer device

## Electro - Optical Air Sterilizer with Ionizer

MODEL NO. 3707UVC

### USER MANUAL

#### FEATURES

##### 1. Air Sterilizing Function

The emission tube in the Sterilizer generates short-wavelength ultra-violet rays for the destruction of bacteria, fungi and virus in the air. The ventilation system will draw air from the outside of machine to the interior of it. The emission tube will then discharge the said ultra-violet rays for the annihilation of bacteria, fungi and virus in the drawn-in air. The purified air will then be driven out into the surrounding atmosphere. The quality of the air in the environment is thus improved.

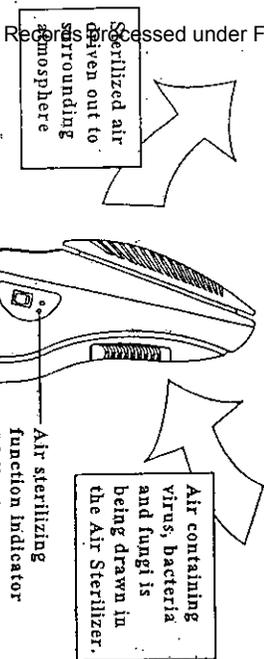
UV-C light has been proven to be an effective way to destroy bacteria, fungi and virus.

##### IMPORTANT NOTE

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More sophisticated masks may go further to 0.3 micron.

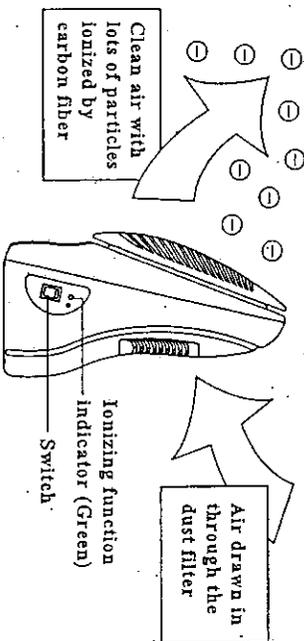
Many infectious viruses have diameters less than 0.1 micron. They go right through these filters, but cannot escape the Ultra-Violet rays extermination.



##### 2. Ionizing Function

The air we breathe is electrically charged with tiny particles, called ions, that revitalize the atmosphere. These naturally charged ions are abundant on the seacoasts, mountaintops, and in the "great outdoors". The process of negative ionization by this ionizer creates a sensation similar to the cleaning of the atmosphere after a rainstorm.

Ionizers produce negative ions to be dispersed into the surrounding air. These ions draw tiny pollutants together to form larger particles, which will then settle onto the floor because of the action of gravity and magnetic effect.



#### APPLICATIONS

##### 1. Air Sterilizing Function

Sterilizing exhaled air from virus carriers while improving quality of air inhaled by users.

##### 2. Ionizing Function

This safety-designed equipment will improve your surrounding air quality. It is perfect for your home and your office. This product can remove pollutants from air such as secondary tobacco smoke, greasy cooking smoke, airborne bacteria, insecticide dust, pet fur, pollen and more.

Suitable for lifts, hospitals, clinics, schools, hotels, karaoke, banks, libraries, restaurants, video game centers, club houses, and other residential, commercial, industrial, and small indoor environment.

#### IMPORTANT SAFETY INSTRUCTIONS

- A slight sensation may be felt if the carbon fiber in the front of air outlet is touched. This is normal and presents no danger. This sensation may also be felt if you touch a person or a large metal object while your other hand is on the unit.

- Always remember to unplug the unit before any cleaning.

- Do not clean the unit by spraying with, or immersing in water.

- Do not insert any object into the openings of the unit.

- If the supply cord is damaged, it must be replaced by the manufacturer or its service agent or similarly qualified person in order to avoid a hazard.

#### INSTALLATION AND OPERATION

No installation is required. Just plug the unit into any standard electrical outlet and operate it by the switch. The air sterilizer and the ionizer will both continuously be operated.

#### PLACEMENT

Never place the unit on or near electronic devices that contain electronic circuits or may be damaged by electrical fields, like audio tapes, video tapes, floppy disks, computers, wrist watches, radios, telephones, etc. Place the product away from non-washable wall to prevent dust accumulation on them.

#### MAINTENANCE

- It is recommended to routine service the unit every two weeks.

- Remember to unplug the unit before any cleaning.

- Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.

- Dust filter - Take off the dust filter and wash it by tap water. Allow it to dry completely before putting it back. Place the filter until it is properly fixed. Never operate the unit without the filter in place.

- Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.

#### TECHNICAL INFORMATION

Operating voltage: 220V-240V 50 Hz

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**Manufacturer Information**

Name of Manufacturer: John Manufacturing Ltd.  
Address: 6/F, Yau Lee Centre, 45 Hoi Yuen Road,  
Kwun Tong, Kowloon, Hong Kong, R.P. China  
Telephone Number: 852-2341-1228  
Fax Number: 852-2343-4319  
Primary Contact Person: Dr. John Yuen  
Alternative Contact Person: Ms. Vivian Lam

**510(k) SUMMARY**  
**Electro-Optical Air Sterilizer with Ionizer**

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510Kk) Summary.

1. **Submitted By:**

Dr. John Yuen  
John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
P.R. China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA  
A GROUP  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Tel: 1-626-581-1290  
Fax: 1-626-581-1291  
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

4. **Proprietary Name:**

Electro-Optical Air Sterilizer with Ionizer

5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.5045 Medical Recirculating Air Cleaner. A device designed to remove particles from air, as class II devices, product code FRF, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

Breathe Easy (RespirAid Ltd.) K981841

8. **Device Description**

**Electro-Optical Air Sterilizer with Ionizer** device is an adjustable and portable personal system for treating air in a specified area of a room. The Electro-Optical Air Sterilizer with Ionizer device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path.

**Electro-Optical Air Sterilizer with Ionizer** device contains also an air filtering system with an Ultraviolet radiation tube and a high negative voltage carbonated fiber, which purified air, is emitted to exhaust frame grid, to further ionized and purified.

**Electro-Optical Air Sterilizer with Ionizer** device employs photoelectrons to eliminate germs, viruses, funguses and airborne microorganisms or particles in the air comprising a three-dimensional housing, an exhaust frame grid. Ionized air is emitted from exhaust frame grid. When air full of germs, viruses, funguses and other harmful airborne microorganisms or particles in the air moved into an air aggregation wall through air aggregator, and then into said air inlet, which is between ultraviolet radiation tube and air aggregation wall. Ultraviolet radiation tube generates extreme ultraviolet to eliminate germs, viruses, funguses and other harmful airborne microorganisms or particles in the air. Then purified air is emitted to exhaust frame grid, to further ionized and purified through high negative voltage carbonated fiber. From exhaust frame grid, fresh air filled with anions is emitted to improve the room air.

9. **Intended Use:**

The **Electro-Optical Air Sterilizer with Ionizer** device is a medical Recirculating air cleaner designed to remove airborne particles all allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites, and harmful fibers, that may lead to allergic reactions.

10. Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Electro-Optical Air Sterilizer with Ionizer** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

11. Substantial Equivalence:

The **Electro-Optical Air Sterilizer with Ionizer** is substantial equivalence to the **BREATHE ESAY** cleared under K981841 in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

Device Name: **Electro-Optical Air Sterilizer with Ionizer**

Indications for Use: **The Electro-Optical Air Sterilizer with Ionizer device is a medical Recirculating air cleaner designed to removed airborne particles all allergens, such as: dust, smoke, pollen, mold spores, animal hair and dander, dust mites, and harmful fibers, that may lead to allergic reactions or respiratory infection.**

*Penicillin*

*1667*

*cause allergy* *etc*

\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
And General Hospital Devices

510(k) Number \_\_\_\_\_

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEED  
Concurrence of CDRH, Office of Device Evaluation (ODE)

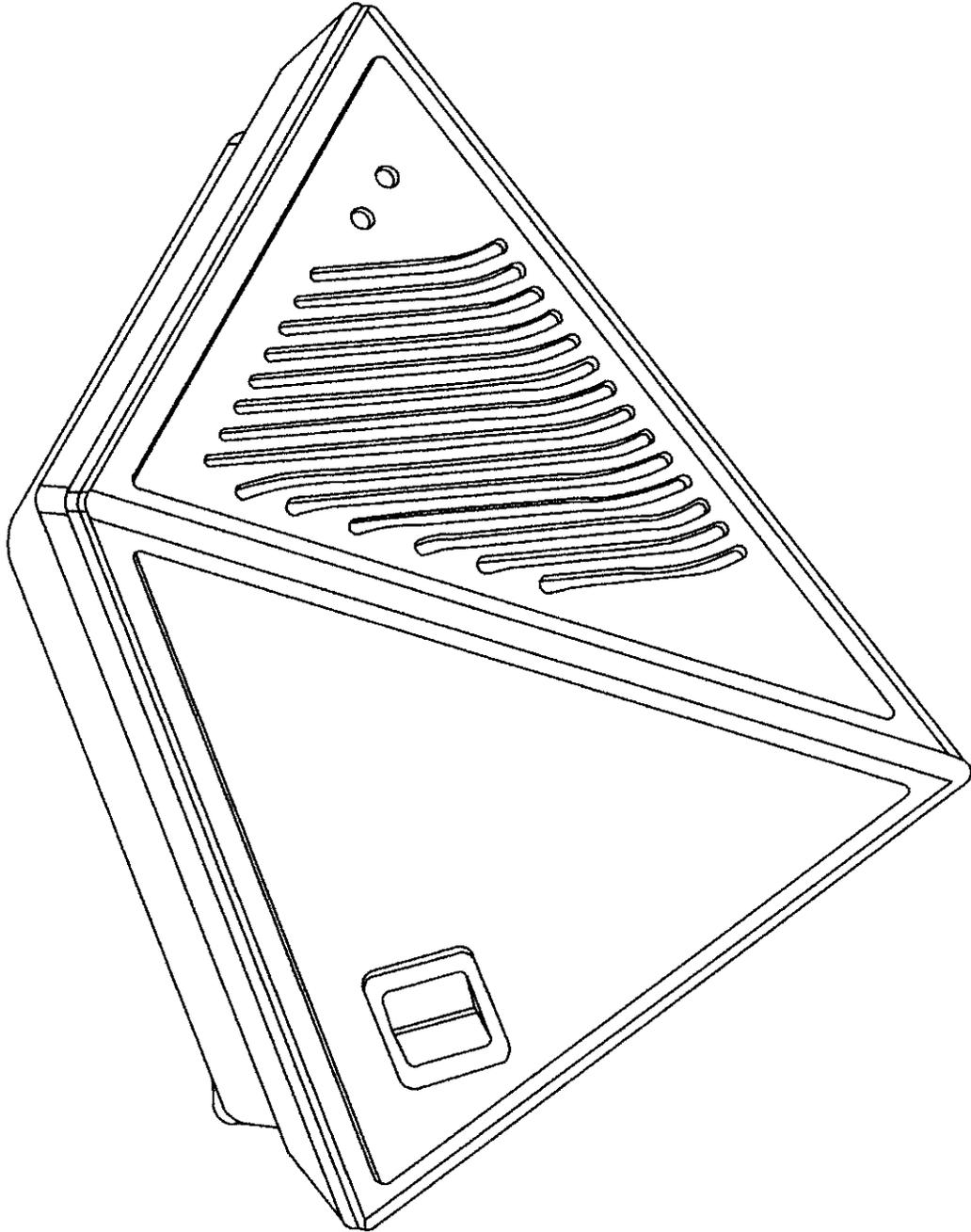
Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_

*167*

Fig. 1









































DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 13 1998

RespirAid Limited  
C/O Ms. Shoshana Friedman  
Push-med Limitd  
117 Ahuzah St. Ra'ananna 43373  
ISRAEL

Re: K981841  
Trade Name: BREATHE EASY, Models AD and CD  
Regulatory Class: II  
Product Code: FRF  
Dated: August 24, 1998  
Received: September 4, 1998

Dear Ms. Friedman:

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 (Pre-market 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

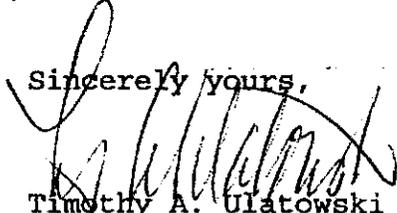
Page 2 - Ms. Friedman

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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" (21CFR 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,

  
Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

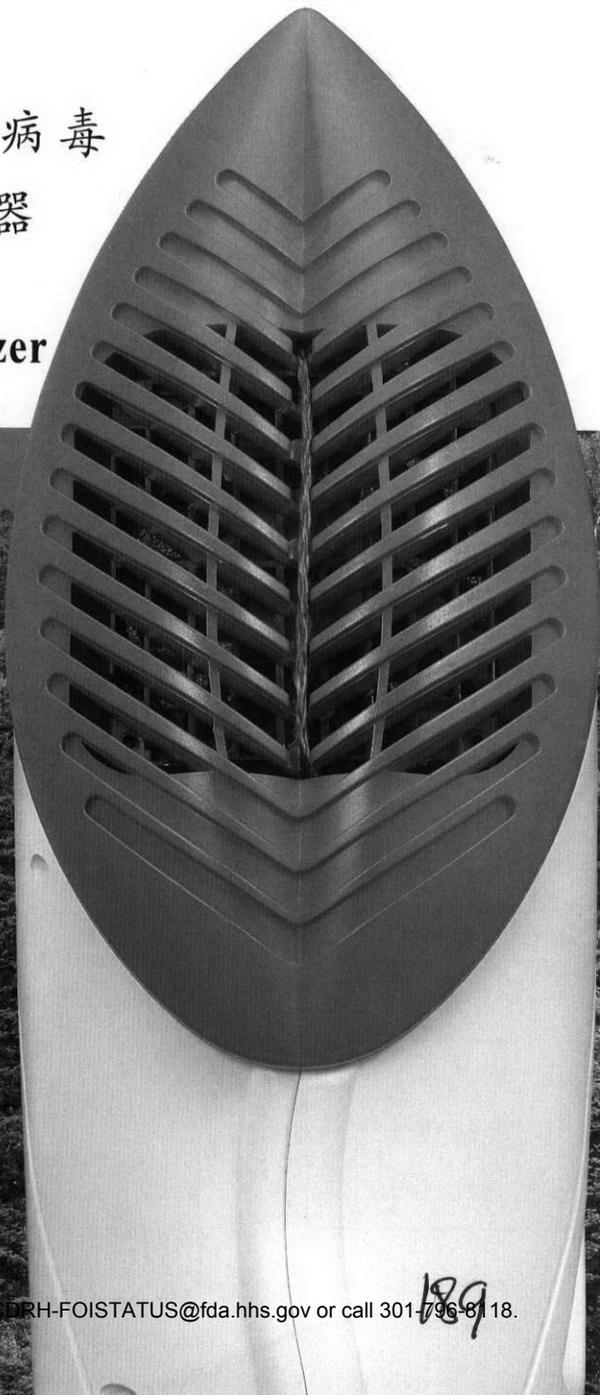
188



祖 科

祖 科 光 電 子 殺 菌 殺 病 毒  
兼 離 子 空 氣 淨 化 器

**Electro-Optical  
Air Sterilizer with Ionizer**



189

MODEL NO. 3707UVC

說明書

特點

1. 光電子殺菌殺病毒功能

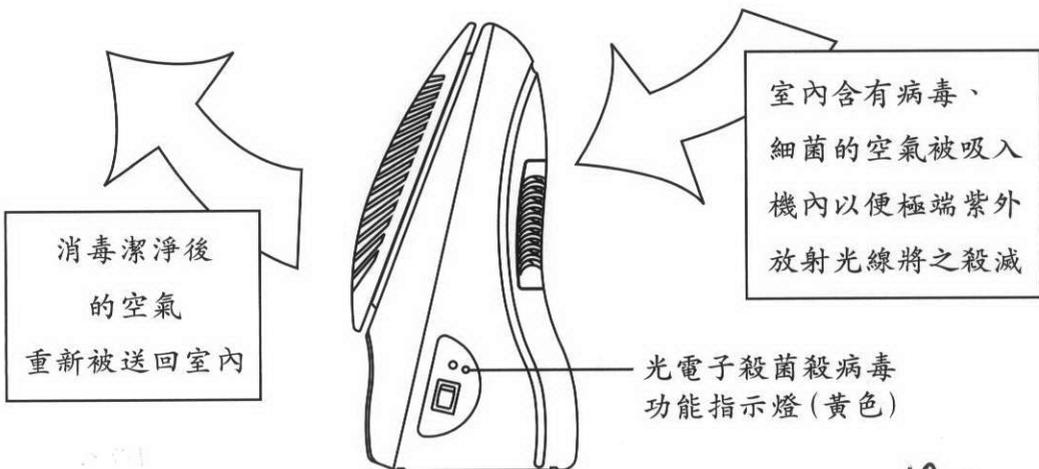
本光電子殺菌殺病毒機的內置發射管，能產生極端紫外放射光線，可以殺滅空氣中的細菌、霉菌和病毒。

本機內置的抽風系統把空氣從室內環境吸進機體內，內置發射管釋放出的極端紫外放射光線，會把吸入空氣中的細菌、霉菌和病毒殺滅。送風系統會把消毒後的空氣送出機外，環境空氣質素因而得到改善。

極端紫外放射光線，經已被證實具有殺滅空氣中的細菌、霉菌和病毒的能力。

注意：

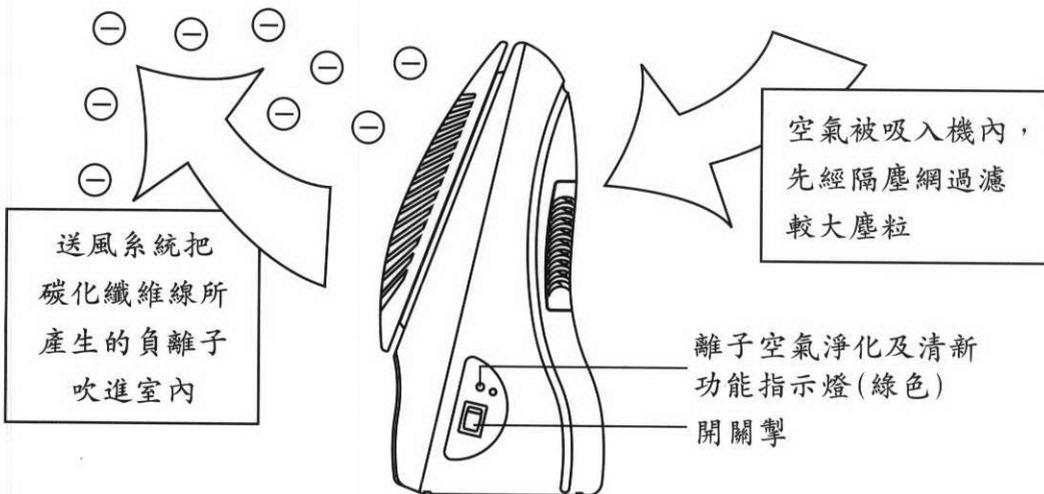
- 一般口罩只能過濾3微米以上的物體，即是說，體積少於3微米的病毒或細菌，不能被有效過濾或隔除。
- 較優良的口罩亦只能過濾小至0.3微米的物體。
- 但很多傳染性病毒直徑小於0.1微米，亦即小於一千萬份之一米，更非一般口罩所能過濾。但本機的極端紫外放射光線則能把他們殺滅。



## 2. 離子空氣淨化及清新功能

我們呼吸的空氣中有很多帶有電荷的離子。而研究發現，我們在海邊、山頂、瀑布旁或綠化郊野裡感到空氣清新和身心舒暢，是因為空氣中的離子濃度極高。這離子空氣淨化器，能釋放大量負離子，增加室內空氣的離子濃度，從而令空氣產生一種如暴風雨過後的清新感覺。

另外，離子空氣淨化器產生大量負離子，而機內的送風系統把負離子送到附近的室內環境。這些帶電荷的負離子會把空氣中的微塵如油煙、花粉等凝聚起來，成為較大的微粒，隨而受地心吸力影響下墜落地面，方便清理。



### 用途

#### 1. 殺菌殺病毒功能

殺滅空氣中的細菌、霉菌和病毒，特別是把帶菌者呼出的空氣消毒，從而改善室內的空氣質素。

#### 2. 離子空氣淨化及清新功能

這個安全設計的空氣淨化器，能大大提高室內的空氣質素。本產品在住宅和辦公室都完全合用。其主要功能是清除空氣中的微塵，包括二手煙、煮食油煙、浮游細菌、殺蟲劑殘留、寵物軟毛、花粉等等。

產品適用於：升降機內、醫院、診所、學校課室、酒店房間、卡拉OK、銀行、

圖書館、餐廳酒樓、遊戲機中心、網吧、會所、住宅、辦公室及

其他室內環境。 Questions? Contact FDA/CDRH/QCCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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## 重要安全事項

Records processed under FOIA Request #2016-966; Released by CDRH on 03-07-2016.

1. 如用手觸及機身前方出氣口附近的碳化纖維線，會有輕微的感覺，這是完全正常。不會有危險。若一手按著機身，另一手接觸大型金屬物，也會產生相同感覺。
2. 清潔機身前，必須先關閉電源，並拔出交流電源插頭。
3. 清潔時，切勿向機身或機內噴水，更不能於任何時間把本機浸於水中。
4. 不要把任何物件放進機內，免生危險。
5. 如電源線受損，必須找維修服務處或合格技術人員進行修理。

## 安裝及操作

無須任何安裝便可使用。只需接上正確電源，便可用開關掣操作本機。  
光電子殺菌殺病毒功能和離子空氣淨化及清新功能 **會同時地運行。**

## 安放位置

請勿把此機靠近以下設備：擁有電子線路的設備或容易受電場破壞的設備如錄音帶、錄影帶、電腦、電腦磁碟、腕表、收音機、電話等。  
請把此機稍稍遠離不能清洗的牆壁，以免塵埃積聚。

## 清理保養

- 每兩星期清理一次。
- 清理前謹記先關閉電源和拔出電源插頭。
- 以家用稀釋清潔劑沾濕軟布，再以濕潤後的軟布在機身外圍清潔，最後以乾布擦拭至乾爽。
- 可用軟毛刷輕輕清理機身前方出氣口附近的碳化纖維線，小心不要損壞碳化纖維線。
- 可把隔塵網取出，用水清洗，待完全乾爽後放回，謹記先把隔塵網穩固安放後才恢復使用本機。
- 千萬不要拆開機身或以任何方法清理機內。

## 規格：

工作電壓: 220V-240V 50 Hz

19Z

# Electro - Optical Air Sterilizer with Ionizer

**MODEL NO. 3707UVC**

## USER MANUAL

### FEATURES

#### 1. Air Sterilizing Function

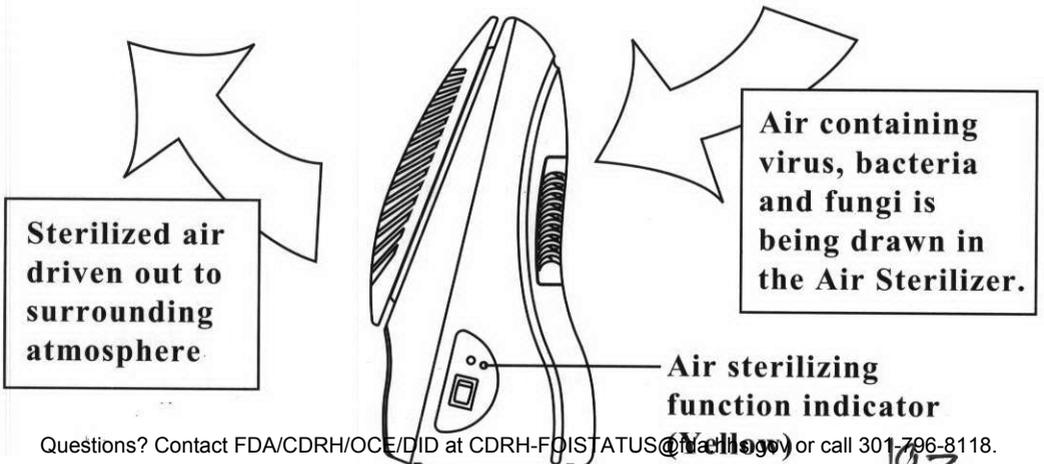
The emission tube in the Sterilizer generates short-wavelength ultra-violet rays for the destruction of bacteria, fungi and virus in the air.

The ventilation system will draw air from the outside of machine to the interior of it. The emission tube will then discharge the said ultra-violet rays for the annihilation of bacteria, fungi and virus in the drawn-in air. The purified air will then be driven out into the surrounding atmosphere. The quality of the air in the environment is thus improved.

UV-C light has been proven to be an effective way to destroy bacteria, fungi and virus.

### IMPORTANT NOTE

- Ordinary masks filter particles down to 3 microns.
- More sophisticated masks may go further to 0.3 micron.
- Many infectious viruses have diameters less than 0.1 micron. They go right through these filters, but cannot escape the Ultra-Violet rays extermination.

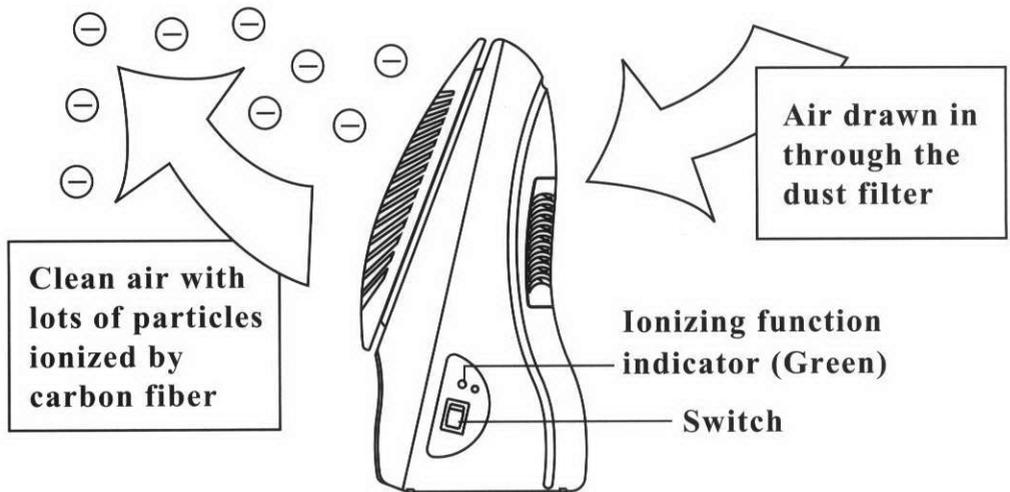


## 2. Ionizing Function

Records processed under FOIA Request #2016-966; Released by CDRH on 03-07-2016.

The air we breathe is electrically charged with tiny particles, called ions, that revitalize the atmosphere. These naturally charged ions are abundant on the seacoasts, mountaintops, and in the "great outdoors". The process of negative ionization by this ionizer creates a sensation similar to the cleaning of the atmosphere after a rainstorm.

Ionizers produce negative ions to be dispersed into the surrounding air. These ions draw tiny pollutants together to form larger particles, which will then settle onto the floor because of the action of gravity and magnetic effect.



## APPLICATIONS

### 1. Air Sterilizing Function

**Sterilizing** exhaled air from virus carriers while **Improving** quality of air inhaled by users.

### 2. Ionizing Function

This safety-designed equipment will improve your surrounding air quality. It is perfect for your home and your office. This product can remove pollutants from air such as secondary tobacco smoke, greasy cooking smoke, airborne bacteria, insecticide dust, pet fur, pollen and more.

**Suitable for lifts, hospitals, clinics, schools, hotels, karaokes, banks, libraries, restaurants, video game centers, club houses, and other residential, commercial, industrial, and small indoor environment.**

## IMPORTANT SAFETY INSTRUCTIONS

- A slight sensation may be felt if the carbon fiber in the front of air outlet is touched. This is normal and presents no danger. This sensation may also be felt if you touch a person or a large metal object while your other hand is on the unit.
- Always remember to unplug the unit before any cleaning.
- Do not clean the unit by spraying with, or immersing in water.
- Do not insert any object into the openings of the unit.
- If the supply cord is damaged, it must be replaced by the manufacturer or its service agent or similarly qualified person in order to avoid a hazard.

## INSTALLATION AND OPERATION

No installation is required. Just plug the unit into any standard electrical outlet and operate it by the switch. The air sterilizer and the ionizer **will both** continually be operated.

## PLACEMENT

Never place the unit on or near electronic devices that contain electronic circuits or may be damaged by electrical fields, like audio tapes, video tapes, floppy disks, computers, wrist watches, radios, telephones, etc.

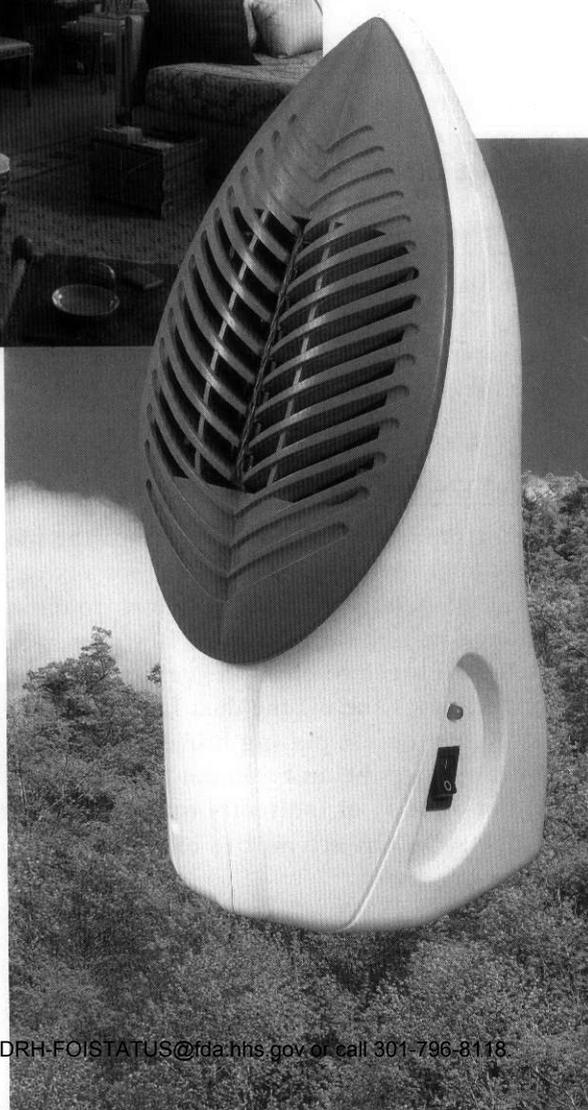
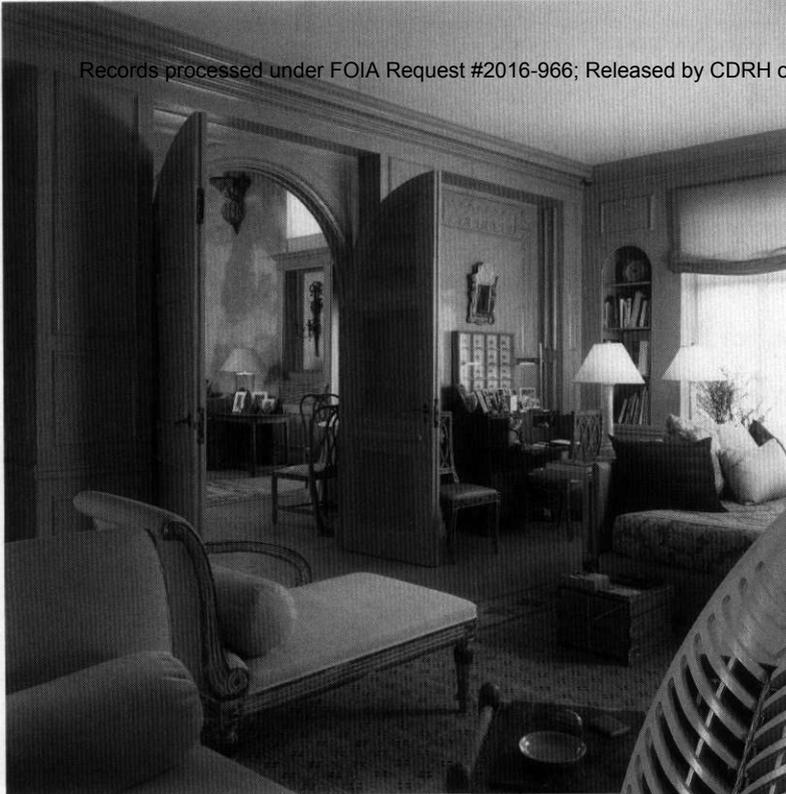
Place the product away from non-washable wall to prevent dust accumulation on them.

## MAINTENANCE

- It is recommended to routine service the unit every two weeks.
- Remember to unplug the unit before any cleaning.
- Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
- Use a soft brush to clean the carbon fiber on the front outlet grill.
- Dust filter - Take off the dust filter and wash it by tap water. Allow it to dry completely before putting it back. Place the filter until it is properly fitted. Never operate the unit without the filter in place.
- Do not directly or indirectly touch the emission tube or other interior parts of the product. **Do not attempt to clean or otherwise tamper with the interior parts of the product.**

## TECHNICAL INFORMATION

Operating voltage: 220V-240V 50 Hz



MODEL NO. 3707UVC

中國發明專利 ZL 03121269.7

中國實用新型 ZL 03242958.4

UK USA HKG

PATENTED & DES.PAT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118  
068-1082 *Mo*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Feli A. Marshall  
Subject: 510(k) Number K033448/S002  
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance?  YES
- Is this device subject to the Tracking Regulation?  YES
- Was clinical data necessary to support the review of this 510(k)?  YES
- Is this a prescription device?  YES
- Was this 510(k) reviewed by a Third Party?  YES
- Special 510(k)?  YES
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) 1/

Animal Tissue Source  YES  NO Material of Biological Origin  YES

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeds

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

FRA/80/II 880-6500  
FRF/80/II 880-5045

Review: Ken Muly Acting IWCB 7/8/04  
(Branch Chief) (Branch Code) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIS@FDA.gov or call 301-796-8178. 2/12/04  
(Division Director) (Date) 4

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: Feli Q. Marshall  
 Division/Branch: DAI0/INCB  
 Device Name: Electro-Optical Air Sterilizer with Ionizer  
 Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?		✓	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?	✓		If NO = Request Data
11. Data Demonstrate Equivalence?	✓		Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

6

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

K033448

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		✓
4. If, not, has POS been notified?		✓
5. Is the product a device?	✓	✓
6. Is the device exempt from 510(k) by regulation or policy?	✓	
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		✓
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		✓
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		✓









July 9, 2004

To: Ms. Feli A. Marshall, Nurse Consultant, INCB, DAGID  
Phone No.: 301-443-8913 Fax No. 301-480-3002  
RE: K033448 Total page: 10

Dear Ms. Feli Marshall:

Regarding the above application, kindly refer the following below in connection to the fax:

1. We have revised the device description.

Please give the undersigned a call at or 626-786-0075 should there is any other concerns or questions that you might encountered.

I thank you very much for your kind attention in this matter and look forward for your approval for the subject device.

Very truly yours,

Arthur King Ma  
For and on behalf of  
John Manufacturing Ltd.

P.S. Please let me know if I need to submit any additional information therefore, I can mail the originals to you.

July 9, 2004

To: Ms. Feli A. Marshall, Nurse Consultant, INCB, DAGID  
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## 510(k) SUMMARY

### Air Purifier 3707 UVC

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510Kk) Summary.

1. **Submitted By:**

Dr. John Yuen  
John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA  
A GROUP  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Tel: 1-626-581-1290      Fax: 1-626-581-1291  
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

**Date Revised:**

April 02, 2004  
June 2, 2004

4. **Proprietary Name:**

**Air Purifier 3707 UVC**5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

AiroCide TiO2 (K023830)

8. **Device Description**

**Air Purifier 3707 UVC** device is an adjustable and portable personal system for treating air in a specified area of a room. **Air Purifier 3707 UVC** device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path. **Air Purifier 3707 UVC** device contains also an air filtering system with an Ultraviolet radiation tube which purified air.

9. **Intended Use:**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

10. **Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Air Purifier 3707 UVC** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

Records processed under FOIA Request #2016-966; Released by CDRH on 03-07-2016.

11. Substantial Equivalence:

The **Air Purifier 3707 UVC** is substantial equivalence to AiroCide TiO2 (K023830) in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

FOIA(b)(7) - Exemption

The air purifier 3707 UVC is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEED**

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Precaution when consumers want to clean and give the subject device a regular maintenancce, the following steps are highly recommended:

1. It is recommended that an Adult User should provide routine service the unit every two weeks.
2. Remember to unplug the unit before any cleaning.

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3. Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
4. Dust filler – Take off the dust filter and wash the dust filter using tap water. Allow it to dry completely before putting it back. Place the filter until it is property fitted. Never operate the unit without the filter in place. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
5. Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.
6. Since the UV lamp is disposable, UV lamp can be replaced when it is burns out. Please unplug the device with any input of electricity before charging the UV lamp. Wash the used UV lamp with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
7. Filter can be replaced as needed. 2 Extra filters are included with purchase. (Normally, it is advised to replace the filter every 6 month even with the regular cleaning in every 2 week to ensure the best results.) Please unplug the device with any inputs of electricity before charging the filter. Wash the used filter with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)

**Table of Comparisons**

Predicate Device	Proposed Device
AiroCide TiO2 (K023830)	Air Purifier 3707 UVC
Classification Name: <b>Medical Ultraviolet Air Purifier</b>	Classification Name: <b>Medical Ultraviolet Air Purifier</b>

Classification: <b>Class II</b> Product Code: <b>FRA</b>	Classification: <b>Class II</b> Product Code: <b>FRA</b>
Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>	Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>
Indication for Use: <b>Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.</b>	Indication for Use: The <b>air purifier 3707 UVC</b> is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.
Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet treated air outlet, a blower, a filter, a heater and humidifier.</b>	Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet, treated air outlet, a blower, a filter, an Ultraviolet radiation tube.</b>
Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.</b>	Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act. However, the Electro-Optical Air Sterilizer with Ionizer device complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.</b>
Conclusion: The AiroCide TiO <sub>2</sub> device is the predicate device to the proposed device, namely, the Air Purifier 3707 UVC device due to their substantially equivalent features.	Conclusion: The Air Purifier 3707 UVC device is substantially equivalent to the AiroCide TiO <sub>2</sub> device due to the substantially equivalent features.

### Instruction of Use

Air Purifier  
Model No. 3707 UVC

**Installation and Operation**

No Installation is required. Just plug the unit into any standard electrical outlet and operate it by the switch.

**Placement**

Never place the unit on or near electronic devices that contain electronic circuits or any flammable gases such as oxygen or gas.

**Warnings:**

Do not use the unit with any extension cord.

Do not use the unit when hands are wet. You may get hurt from electric shock from water contact.

Do not operate the unit near any flammable gases or oxygen.

Do not operate the unit at any outdoor as it is designed for indoor use.

Do not block any opening of the unit.

Never let children to operate the unit.

Always unplug the unit before performing any maintenance.

Manufacturer: John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

Telephone: 852-2341-1228

USA Contact: A GROUP Incorporated  
18780 Amar Road, STE 202-203  
Walnut, CA 91789

Telephone 626-581-1290

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Feli Marshall  
Subject: 510(k) Number K033448/S'  
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

*Tel. Held see memo dated 5/11/04*

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed *to be reviewed.*
- A 510(k) summary OR  A 510(k) statement *to be reviewed*
- The required certification and summary for class III devices
- The indication for use form *to be reviewed*

Combination Product Category (Please see algorithm on H drive 510k/Boilers) \_\_\_\_\_

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

FEP/89/II 880.5045  
FRA/89/II 880.6500

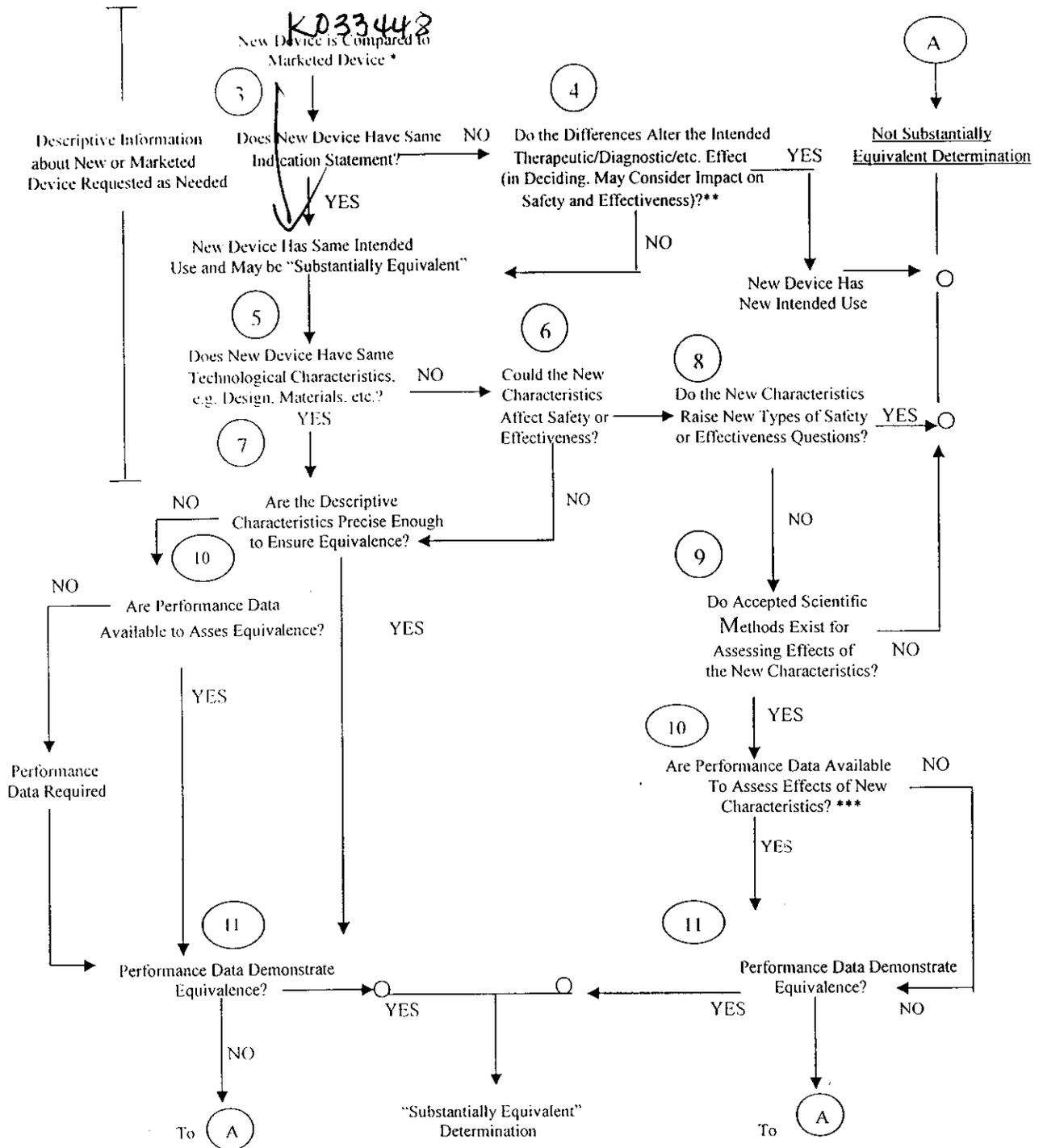
Review: Ken Muley Acting INCB  
(Branch Chief) (Branch Code)

5/12/04  
(Date)

Final Review: \_\_\_\_\_

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

608

Records processed under FOIA Request #2016-966; Released by CDRH on 03-07-2016.

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*

TRANSMISSION OK

TX/RX NO	3899
CONNECTION TEL	916265811291
SUBADDRESS	
CONNECTION ID	
ST. TIME	05/11 20:53
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PGS.	6
RESULT	OK

**DHHS/PHS/FDA/CDRH**  
**DIVISION OF ANESTHESIOLOGY,**  
**GENERAL HOSPITAL, INFECTION CONTROL**  
**AND DENTAL DEVICES**  
**9200 CORPORATE BOULEVARD**  
**HFZ-480**  
**ROCKVILLE, MARYLAND 20850**



DATE: 5/11/04

FROM: ms. Feli Marshall

TO: Arthur man

PHONE #: 626-581-1290

FAX #: 626-581-1291

SUBJECT: K033448

enclosures: Truthful + Accurate  
 ① Statement  
 ② Indication for the format.

ADDITIONAL COMMENTS: Request for Additional Information 69

DHHS/PHS/FDA/CDRH  
DIVISION OF ANESTHESIOLOGY,  
GENERAL HOSPITAL, INFECTION CONTROL  
AND DENTAL DEVICES  
9200 CORPORATE BOULEVARD  
HFZ-480  
ROCKVILLE, MARYLAND 20850



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PHONE #: 626-581-1290

FAX #: 626-581-1291

SUBJECT: K033448

ADDITIONAL COMMENTS: Request for Additional Information

Enclosures x 2 (Indication for use + Truthful + Accurate Statement)

# OF PAGES & COVER SHEET: 5 including face sheet

PHONE NO: (301) <sup>443-8913</sup> 443-8879

FAX NO: (301) 480-3002

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) 1/5/04 Feli A. Marshall  
Subject: 510(k) Number K 033448  
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

*Telephone held  
see memo dated  
1/5/03*

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement *to be revised*
- The required certification and summary for class III devices
- The indication for use form *to be revised*

Combination Product Category (Please see algorithm on H drive 510k/Boilers) No

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

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Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

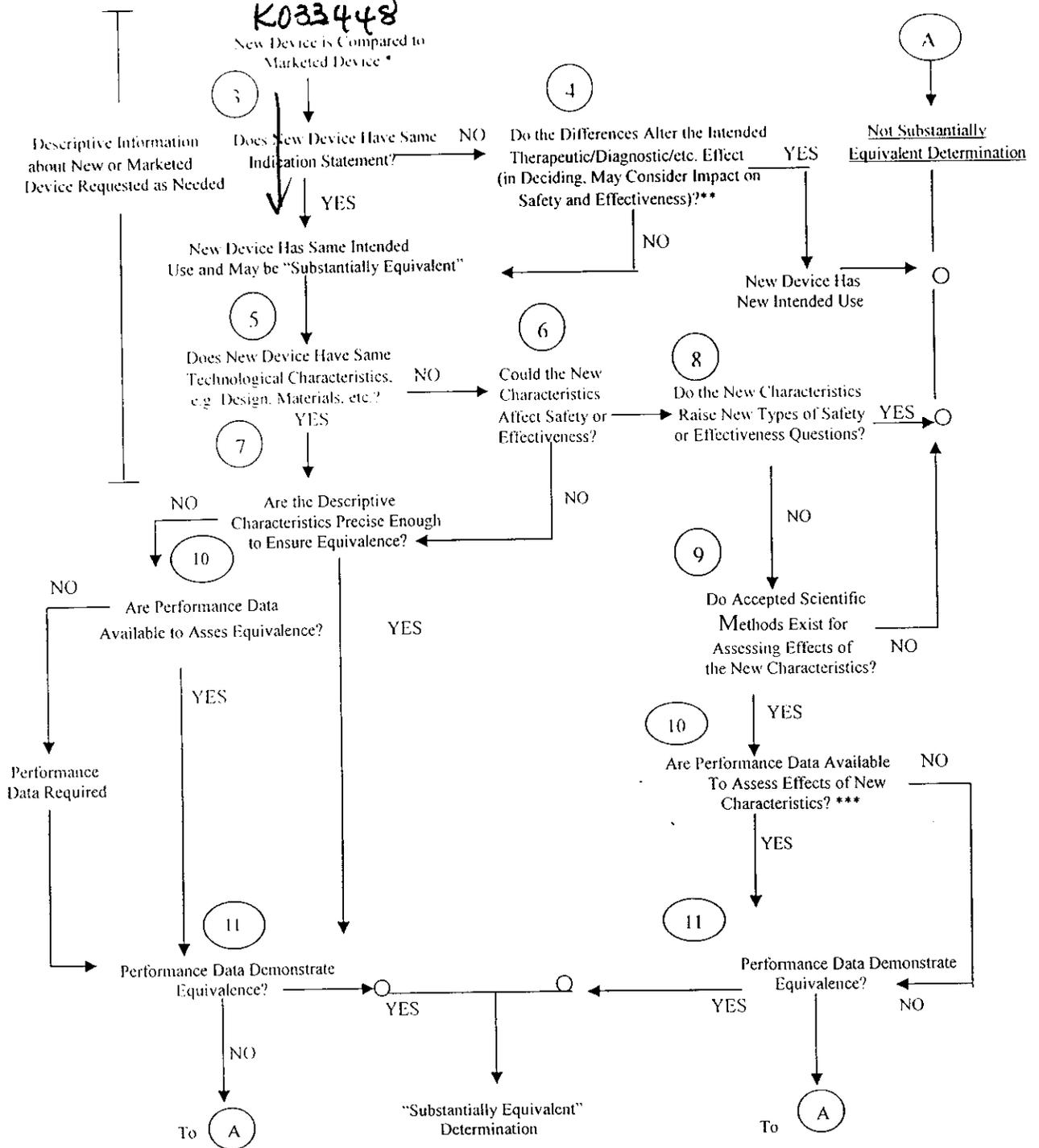
FRA179/II ? FRF180/II

Review: [Signature] [Signature] 1/6/04  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_ (Date)  
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.  
(Division Director)

*(14)*

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



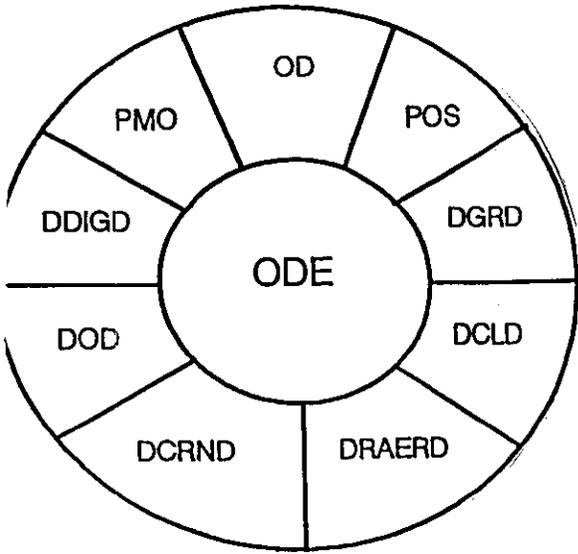
\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

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115

**DHHS/PHS/FDA/CDRH**  
**DIVISION OF DENTAL, INFECTION CONTROL,**  
**AND GENERAL HOSPITAL DEVICES**  
**9200 CORPORATE BOULEVARD, HFZ-420**  
**ROCKVILLE, MARYLAND 20850**



**DATE:** *Jan. 5, 2004*

**FROM:** *ms. Feli Marshall*

**NO. OF PAGES:** *5*

**PHONE NO:** *301-443-8913* ~~8879~~

**FAX NO:** *301-480-3002*

*Transmitted*

**TO:** *Arthur King Man*

**FAX NO:** *626-581-1291*

**SUBJECT:** *K033448*

**ADDITIONAL COMMENTS:** *Request for Additional Information*

*Thank you,  
Feli*

*Enclosure: Truthful + Accurate Statement*

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER FEDERAL LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.





























## SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K033448

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

### Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510]] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510]] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510]] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

\* - May not be applicable for Special 510(k)s.

\*\* - Required for Class III devices, only.

\*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510]] Manual and the

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

\* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening  Yes  No

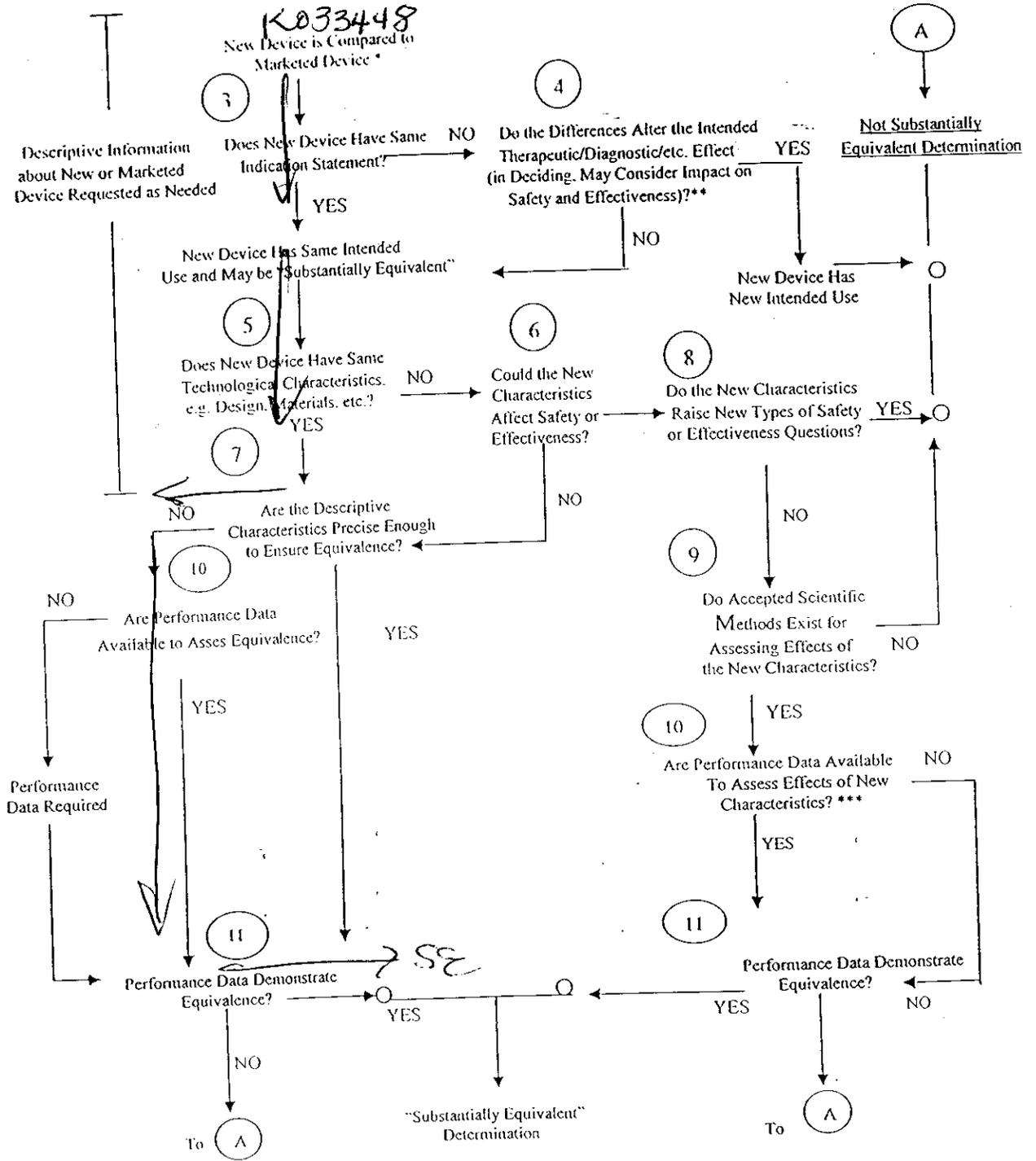
Reviewer: \_\_\_\_\_

Concurrence by Review Branch: NOV = 5 2016

Date: \_\_\_\_\_

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

### 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



• 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

•• This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or call 301-796-8118.

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

April 19, 2004

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

JOHN MFG., LTD.  
C/O A GROUP  
18780 AMAR ROAD, STE 203-203  
WALNUT, CA 91789  
ATTN: ARTHUR KING MA

510(k) Number: K033448  
Product: ELECTRO-OPTICAL  
AIR STERILIZER  
WITH IONIZER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health



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Contact Person	01
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## 510(k) SUMMARY

### Air Purifier 3707 UVC

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510Kk) Summary.

1. **Submitted By:**

Dr. John Yuen  
John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA  
A GROUP  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Tel: 1-626-581-1290  
Fax: 1-626-581-1291  
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

**Date Revised:**

April 02, 2004

4. **Proprietary Name:**

Air Purifier 3707 UVC

5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

AiroCide TiO2 (K023830)

8. **Device Description**

**Air Purifier 3707 UVC** device is an adjustable and portable personal system for treating air in a specified area of a room. **Air Purifier 3707 UVC** device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path.

**Air Purifier 3707 UVC** device contains also an air filtering system with an Ultraviolet radiation tube which purified air.

**Air Purifier 3707 UVC** device employs Ultraviolet radiation tube to eliminate germs, viruses, funguses and airborne microorganisms or particles in the air. When air full of germs, viruses, funguses and other harmful airborne microorganisms or particles in the air moved into the device, ultraviolet radiation tube generates ultraviolet to eliminate germs, viruses, funguses and other harmful airborne microorganisms or particles in the air. Then purified air is emitted to exhaust frame.

9. **Intended Use:**

The potential application for **Air Purifier 3707 UVC** include removing airborne particles, and/or dust, smoke, pollen, mold spores animal hair, dust mites and harmful fibers present in rooms or enclosed areas such as elevators, karaoke bar, treatment rooms, hospital wards, intensive care hospital wards, office areas, vehicles and industrial buildings.

10. **Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Air Purifier 3707 UVC** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

11. Recommendation for placement of number of device vs. room/enclosed area size.

Each Air Purifier 3707 UVC unit can treat 200 Sq. Ft.

*Room? space*

Air Purifier 3707 UVC has a flat base so that consumers can put the device almost anywhere they want.

12. Substantial Equivalence:

The **Air Purifier 3707 UVC** is substantial equivalence to AiroCide TiO<sub>2</sub> (K023830) in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

Precaution when ~~consumers~~ want to clean and give the subject device <sup>Full</sup> a regular maintenance, the following steps are highly recommended:

1. It is recommended to routine service the unit every two weeks.
2. Remember to unplug the unit before any cleaning.
3. Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
4. Use a soft brush to lean the carbon fiber on the front outlet grill.
5. Dust filler - Take off the dust filter and wash it by tap water. Allow it to dry completely before putting it back. Place the filter until it is property fitted. Never operate the unit without the filter in place.
6. Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.
7. *When do you change the UV lamp? How often change*

Since all the fungus, and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.

**(The forgoing maintenance information was/will be printed in the user manual.)**

Table of Comparisons

Predicate Device	Proposed Device
AiroCide TiO2 (K023830)	Air Purifier 3707 UVC
Classification Name: <b>Medical Ultraviolet Air Purifier</b>	Classification Name: <b>Medical Ultraviolet Air Purifier</b>
Classification: <b>Class II</b> Product Code: <b>FRA</b>	Classification: <b>Class II</b> Product Code: <b>FRA</b>
Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>	Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>
Indication for Use: <b>Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.</b>	Indication for Use: <b>The potential application for air purifier 3707 UVC</b> include removing airborne particles, and/or dust, smoke, pollen, mold spores animal hair, dust mites and harmful fibers present in rooms or enclosed areas such as elevators, karaoke bar, treatment rooms, hospital wards, intensive care hospital wards, office areas, vehicles and industrial buildings.
Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit,, an air inlet treated air outlet, a blower, a filter, a heater and humidifier.</b>	Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet, treated air outlet, a blower, a filter, an Ultraviolet radiation tube.</b>
Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.</b>	Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.</b> However, the Electro-Optical Air Sterilizer with Ionizer device complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.
Conclusion: The AiroCide TiO2 device is the predicate device to the proposed device, namely, the Air Purifier 3707 UVC device due to their substantially equivalent features.	Conclusion: The Air Purifier 3707 UVC device is substantially equivalent to the AiroCide TiO2 device due to the substantially equivalent features.

INDICATIONS FOR USE

510(k) Number (if known): K033448

Device Name: **Air Purifier 3707 UVC**

Indications for Use:

The potential application for **air purifier 3707 UVC** include ~~removing~~ airborne particles, and/or dust, smoke, pollen, mold spores animal hair, dust mites and harmful fibers present in rooms or enclosed areas such as elevators, karaoke bar, treatment rooms, hospital wards, intensive care hospital wards, office areas, ~~vehicles and industrial buildings~~.

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\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
And General Hospital Devices

510(k) Number: K033448

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_



























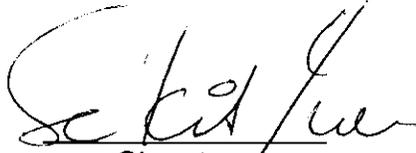




Truthful and Accurate Statement

*7/23/2016 11:16 AM  
Company name  
missing*

I, John Yuen, believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Signature

YUEN, John  
Submitter

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Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

June 30, 2004

JOHN MFG., LTD.  
C/O A GROUP  
18780 AMAR ROAD, STE 203-203  
WALNUT, CA 91789  
ATTN: ARTHUR KING MA

510(k) Number: K033448  
Product: ELECTRO-OPTICAL  
AIR STERILIZER  
WITH IONIZER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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**PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT\***  
(As Required By 21 CR 807.87 (j))

I certify that, in my capacity as President of John Manufacturing Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
Yuen, Se Kit

\_\_\_\_\_  
May 1, 2004

\_\_\_\_\_  
K 033448

**\*Must be signed by a responsible person of the firm required to submit the premarket notification (e.g., not a consultant for the 501(k) submitter.)**

1033448

## 510(k) SUMMARY

### Air Purifier 3707 UVC

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510Kk) Summary.

1. **Submitted By:**

Dr. John Yuen  
John Manufacturing Ltd.,  
6/F., Yau Lee Center, 45 Hoi Yuen Road,  
Kwun Tong, Hong Kong  
China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA  
A GROUP  
18780 Amar Road, STE 202-203  
Walnut, CA 91789  
Tel: 1-626-581-1290      Fax: 1-626-581-1291  
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

**Date Revised:**

April 02, 2004

June 2, 2004

4. **Proprietary Name:**

Air Purifier 3707 UVC

5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

AiroCide TiO2 (K023830)

8. **Device Description**

**Air Purifier 3707 UVC** device is an adjustable and portable personal system for treating air in a specified area of a room. **Air Purifier 3707 UVC** device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path. **Air Purifier 3707 UVC** device contains also an air filtering system with an Ultraviolet radiation tube which purified air.

**Air Purifier 3707 UVC** device employs Ultraviolet radiation tube to eliminate germs, viruses, funguses and airborne microorganisms or particles in the air. When air full of germs, viruses, funguses and other harmful airborne microorganisms or particles in the air moved into the device, ultraviolet radiation tube generates ultraviolet to eliminate germs, viruses, funguses and other harmful airborne microorganisms or particles in the air. Then purified air is emitted to exhaust frame.

9. **Intended Use:**

The potential application for **Air Purifier 3707 UVC** include removing airborne particles, and/or dust, smoke, pollen, mold spores animal hair, dust mites and harmful fibers present in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards (away from oxygen and other flammable gases).

10. **Performance Standards:**

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Air Purifier 3707 UVC** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

11. Substantial Equivalence:

The **Air Purifier 3707 UVC** is substantial equivalence to AiroCide TiO<sub>2</sub> (K023830) in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

### Indications for Use

510(k) Number (if known): K033448

Device Name: *Product* **Air Purifier 3707 UVC**

Indications for Use: ~~The potential application for air purifier 3707 UVC include~~  
~~removing~~ airborne particles, and/or dust, smoke, pollen, mold spores animal hair, dust  
mites and harmful fibers present in rooms or enclosed areas such as treatment rooms,  
hospital wards, intensive care hospital wards. (away from oxygen and other flammable  
gases).

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Precaution when consumers want to clean and give the subject device a regular maintenance, the following steps are highly recommended:

1. It is recommended that an Adult User should provide routine service the unit every two weeks.
2. Remember to unplug the unit before any cleaning.
3. Clean the outside of the unit and surroundings with a damp cloth moistened with common household detergent. Dry it up afterwards.
4. Dust filler – Take off the dust filter and wash the dust filter using tap water. Allow it to dry completely before putting it back. Place the filter until it is properly fitted. Never operate the unit without the filter in place. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
5. Do not directly or indirectly touch the emission tube or other interior parts of the product. Do not attempt to clean or otherwise tamper with the interior parts of the product.
6. Since the UV lamp is disposable, UV lamp can be replaced when it is burns out. Please unplug the device with any input of electricity before charging the UV lamp. Wash the used UV lamp with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)
7. Filter can be replaced as needed. 2 Extra filters are included with purchase. (Normally, it is advised to replace the filter every 6 month even with the regular cleaning in every 2 week to ensure the best results.) Please unplug the device with any inputs of electricity before charging the filter. Wash the used filter with tap water and put it in a garage bag before disposing. (CAUTION: Even all the fungus and airborne particles would become carbonaceous dust after the treatment by the ultraviolet radiation tube and there should be no harm for consumers but consumers are advised to put on gloves when cleaning the Air Purifier 3707 UVC.)

**Table of Comparisons**

Predicate Device	Proposed Device
AiroCide TiO2 (K023830)	Air Purifier 3707 UVC
Classification Name: <b>Medical Ultraviolet Air Purifier</b>	Classification Name: <b>Medical Ultraviolet Air Purifier</b>
Classification: <b>Class II</b> Product Code: <b>FRA</b>	Classification: <b>Class II</b> Product Code: <b>FRA</b>
Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>	Regulation No.: <b>880.6500</b> Reviewed By: <b>General Hospital Devices</b>
Indication for Use: <b>Potential applications include removing and mineralizing airborne contaminations of pathogens and/or harmful molds and volatile organic compounds present in rooms or enclosed areas: treatment rooms, hospital wards, intensive care hospital wards, holding areas in jails, operating rooms, homeless shelters, pediatric waiting areas, command and control vehicles, embalming rooms in funeral homes, postal facilities, etc.</b>	Indication for Use: <b>The potential application for air purifier 3707 UVC</b> include removing airborne particles, and/or dust, smoke, pollen, mold spores animal hair, dust mites and harmful fibers present in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards (away from oxygen and other flammable gases).
Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet treated air outlet, a blower, a filter, a heater and humidifier.</b>	Device Description: Mobility: <b>Adjustable and portable</b> Parts/Elements: <b>A housing unit, an air inlet, treated air outlet, a blower, a filter, an Ultraviolet radiation tube.</b>
Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.</b>	Performance Standards: <b>No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug, and Cosmetic Act.</b> However, the Electro-Optical Air Sterilizer with Ionizer device complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.
Conclusion: The AiroCide TiO2 device is the predicate device to the proposed device, namely, the Air Purifier 3707 UVC device due to their substantially equivalent features.	Conclusion: The Air Purifier 3707 UVC device is substantially equivalent to the AiroCide TiO2 device due to the substantially equivalent features.

## **Instruction of Use**

Air Purifier  
Model No. 3707 UVC

### **Installation and Operation**

No Installation is required. Just plug the unit into any standard electrical outlet and operate it by the switch.

### **Placement**

Never place the unit on or near electronic devices that contain electronic circuits or any flammable gases such as oxygen or gas.

### **Warnings:**

Do not use the unit with any extension cord.

Do not use the unit when hands are wet. You may get hurt from electric shock from water contact.

Do not operate the unit near any flammable gases or oxygen.

Do not operate the unit at any outdoor as it is designed for indoor use.

Do not block any opening of the unit.

Never let children to operate the unit.

Always unplug the unit before performing any maintenance.

Manufacturer: John Manufacturing Ltd.,  
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Kwun Tong, Hong Kong  
China

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