DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 20, 2016

Toul Meditech AB
Tomas Hansson
CEO
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Västerås, 721 37 SE

Re: K153498
Trade/Device Name: Operio
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus For A Surgical Operating Room
Regulatory Class: Class II
Product Code: ORC
Dated: January 7, 2016
Received: January 14, 2016

Dear Tomas Hansson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely yours,

Michael J. Ryan -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K153498

Device Name
Operio

Indications for Use *(Describe)*
Operio is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site during ophthalmic surgery and to the sterile instruments used during surgery. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter to reduce the microorganisms to a level of < 5 CFU per m3 at the surgical site and instruments.

The air flow is intended to be directed parallel to the surgical site and/or instruments within: 20" (50 cm) in width, 47" (120 cm) in length and 15" (40 cm) in height. Device effectiveness may not be reliably detectable at a distance of 47 inches (120 cm) from the air flow outlet, and effectiveness depreciates beyond this specified area.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submission information

Submission date: 4th of December 2015

510(k) submitter: Tomas Hansson
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Device information

Trade name: Operio

Common name: Air zone unit

Classification name: Air-handling apparatus for a surgical operating room

Regulation number 21 CFR 878.5070

Product code ORC

Device class II

Legally marketed predicate device

Identification of the legally marketed predicate device to which Toul Meditech AB claims SE for.

Code	Manufacturer	Device	510(k) #
ORC	Nimbic, Inc	Air Barrier System	K123006

Device description

The air zone unit Operio is used in a surgical operating room for cleaning the air in a given area by re-circulating the ambient air and cleaning it from airborne particles. The air is filtered through a HEPA filter and the air is generated over the areas where the demands of clean air are especially high. The air zone unit Operio is equipped with a control panel for adjustments and for positioning of the unit.

The air zone unit Operio is a mobile unit that with the help of castors easily can be moved around the patient to an optimal position or, when needed, transported inside the hospital between wards. It is also equipped with an optional instrument tray.

By using a unique sterile shield as a protective barrier the air zone unit can be placed close to the OR table and deliver HEPA filtered air to the surgical site and instruments to reduce the presence of airborne particulate and microorganisms.

Indications for use

Operio is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site during ophthalmic surgery and to the sterile instruments used during surgery. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter to reduce the microorganisms to a level of < 5 CFU per m3 at the surgical site and instruments.

The air flow is intended to be directed parallel to the surgical site and/or instruments within: 20" (50 cm) in width, 47" (120 cm) in length and 15" (40 cm) in height. Device effectiveness may not be reliably detectable at a distance of 47 inches (120 cm) from the air flow outlet, and effectiveness depreciates beyond this specified area.

Difference from predicate device:

The air zone unit Operio is suitable for ophthalmic surgery and sterile instruments used during surgery. It is possible to deliver the clean air without coming into contact with the patient or compromising the work space required by surgical staff. The clean air flow can also be used over instruments and the area of the air flow is bigger compared to the predicate device.

The difference in indications for use compared to the predicate device does not introduce any new hazards and test results can confirm that the subject device is as safe and as effective for use.

Summary of technological characteristics compared to predicate devices

The subject device Operio differs from the predicate device in that it doesn't use a sterile nozzle and device does not depend on attachment to the patient. The subject device requires a single use sterile shield which functions as an equipment cover as well as to direct the non-turbulent flow to the surgical site. The sterile shield is attached to the unit and is not in contact with the patient.

To eliminate contaminated particles entering the surgical site, HEPA filtration is used by both the predicate device and the subject device. The efficiency of HEPA filtration of the subject

device has a higher precision than the predicate device (subject device guarantees 99.995 % compared to 99.97 % for the predicate device).

Comparison table:

Characteristic	Subject device	Predicate device
Review Panel	General Hospital	General Hospital
Indications for use	Operio is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site during ophthalmic surgery and to the sterile instruments used during surgery. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter to reduce the microorganisms to a level of < 5 CFU per m3 at the surgical site and instruments. The air flow is intended to be directed parallel to the surgical site and/or instruments within: 20" (50 cm) in width, 47" (120 cm) in length and 15" (40 cm) in height. Device effectiveness may not be reliably detectable at a distance of 47 inches (120 cm) from the air flow outlet, and effectiveness depreciates beyond this specified area.	The Air Barriers system is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty and posterior vertebral fusion and laminoplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical surface with no gap between the bottom of the nozzle and the surface, (2) the incision plane is parallel with the direction of air flow, and (3) the Incision dimensions are within: 6' (15.2 cm) in width and 20b (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area.
Physical Dimension	24 x 18 x 47-67 inches	11 x 11 x 25 inches
Weight	92 lb	48 lb
Material	Aluminium, powder coated steel, ABS plastic, stainless steel	Stainless steel
Electrical Specifications	1. Mains power input: 120 V (AC), 60 Hz 2. Power consumption: 290 VA	1. Mains power input: 120 V (AC), 60 Hz 2. Unknown
Type of device	Prescription use	Prescription use
Movability	Operio is a portable unit.	The Air Barrier System is a portable unit.

Air filtration	HEPA filtered air with at least 99.995% efficiency against 0.3 µm particles	HEPA filtered air with at least 99.97% efficiency against 0.3 µm particles
HEPA filter media	Nelior membrane media. Folded sheets of nelior.	Continuous pleated glass microfiber
Air inlet Pre-filter Media	Polyamide mesh	Polyurethane Foam
Regular maintenance	HEPA filter to be replaced after 2000 hours/yearly.	Annual
Airflow capacity	Airflow is 235 CFM (400 m3/h)	Airflow 150 CFM
Efficiency	Bacteria carrying particles at the surgical site is 0.4 CFU/m3.	Bacteria carrying particles in the surgical incision is 1.57 CFU/m3
Air volume delivered to incision in CFM	Airflow over surgical site is 235 CFM (400 m3/h)	41
Measured average particulate density at surgical incision	1.1 particulate of 0.5 µm/f³	68,122 particulate of 0.5 µm/f³
Air flow position	Air flow is provided over the surgical site and instruments. No attachment to the patient is necessary.	Air flow is provided to an attachment, nozzle, attached on the patient near the surgical site.
Sterilization	Single-use sterile shield.	Sterile single use.
Sterility Assurance (SAL)	10^{-6} SAL	10^{-6} SAL
Sterilization Method	Gamma irradiation	ETO

Summary of testing

The performance characteristics of the air zone unit Operio have been obtained through both a series of tests, clinical and non-clinical, and performance specifications. Particulate test and CFU test results clearly meet the criteria for achieving reduction of airborne contamination at the intended surgical site and over instruments. The efficiency of HEPA filtration has been tested and is found better than the predicate device.

In testing, the predicate demonstrated a level of particulate presence by 68,122 particles of 0.5 µm/f³, while the subject device had a level of particulates by 1.1 particles of 0.5 µm/f³.

The predicate device demonstrated a reduction from 10.73 to 1.60 CFU's whereas the subject device demonstrated a reduction from 48.2 to 0.4 CFU in a clinical environment.

The following non-clinical tests has been conducted: Simulated use test, Particulate counting test, Colony Forming Units counting test, Air velocity test, Air leakage test, Smoke test and Turbulence tests to demonstrate air flow patterns.

The following standards have been used for performance testing:

- IEC/EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC/EN 60601-1-2:2007 Medical electrical equipment - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Summary of clinical testing

Clinical tests have been carried out in surgical procedures such as Ophthalmology. Measurements where made near the surgical site and over the instruments where the results demonstrated a statistically significant reduction in CFU levels as well as particulates. The CFU value is based on 31 samples from 23 patients. The clinical tests have been carried out in a Swedish University Hospital. As a mean value, the subject device had a CFU counting of 0.4. For particulate counting, the subject device had a mean value of 1.1 particles of 0.5 µm/f³.

Since both particulate counts and CFU level doesn't exceed the predicate device in a clinical environment it is concluded that substantial equivalence is achieved as clinical validation.

Conclusion

Based on a comparison of the performance characteristics, the tests performed, clinical and non-clinical, it is concluded that the subject device Operio is substantially equivalent to the predicate device and therefore is as safe and as effective.