December 20, 2017

Toul Meditech AB
Tomas Hansson
CEO
Tunbytorpsgatan 31
Vasteras, 72137 SE

Re: K173349
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: October 25, 2017
Received: October 25, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K173349

Device Name
Operio

Indications for Use *(Describe)*
Operio is a portable device for use in a surgical operating environment that produces a directed, non-turbulent flow of air to the surgical site during ophthalmic, orthopedic and neuro 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: 12th of October 2017

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	Toul Meditech AB	Operio	K153498

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 environment that produces a directed, non-turbulent flow of air to the surgical site during ophthalmic, orthopedic and neuro 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.

Summary of technological characteristics compared to predicate devices

The difference for the subject device compared to the predicate device is additional and extended claims in the indications, to include neurosurgery and orthopedic surgery. The subject device and predicate device is the same model and identical in technology and characteristics. The use with additional claims do not introduce any new hazards and test results can confirm that the subject device is safe and effective for use.

Comparison table:

Characteristic	Subject device	Predicate device
	Operio	Operio K153498
Review Panel	General Hospital	General Hospital
Indications for use	Operio is a portable device for use in a surgical operating environment that produces a directed, non-turbulent flow of air to the surgical site during ophthalmic, orthopedic and neuro 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 m^3 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.	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 m^3 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.
Physical Dimension	24 x 18 x 47-67 inches	24 x 18 x 47-67 inches
Weight	92 lb	92 lb
Material	Aluminium, powder coated steel, ABS plastic, stainless steel	Aluminium, powder coated steel, ABS plastic, 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. Power consumption: 290 VA
Type of device	Prescription use	Prescription use
Movability	Operio is a portable device	Operio is a portable device
Air filtration	HEPA filtered air with at least 99.995% efficiency against 0.3 µm particles	HEPA filtered air with at least 99.995% efficiency against 0.3 µm particles
HEPA filter media	Nelior membrane media. Folded sheets of nelior.	Nelior membrane media. Folded sheets of nelior.
Air inlet Pre-filter Media	Polyamide mesh	Polyamide mesh
Regular maintenance	HEPA filter to be replaced after 2000 hours/yearly.	HEPA filter to be replaced after 2000 hours/yearly.
Airflow capacity	Airflow is 235 CFM	Airflow is 235 CFM
Efficiency	Bacteria carrying particles at the surgical sites are 0.4, 2 and 0.52 CFU/m3.	Bacteria carrying particles at the surgical site is 0.4 CFU/m3.

Airflow speed	0.4 m/s	0.4 m/s
Air volume delivered to incision in CFM	Airflow over surgical site is 235 CFM	Airflow over surgical site is 235 CFM
Measured average particulate density at surgical incision	1.1 particulate of 0.5 µm/f³	1.1 particulate of 0.5 µm/f³
Air flow position	Air flow is provided over the surgical site and instruments.	Air flow is provided over the surgical site and instruments.
Sterile accessory	Single-use sterile shield from Toul Meditech.	Single-use sterile shield from Toul Meditech.
Sterility Assurance (SAL)	10^{-6} SAL	10^{-6} SAL
Sterilization Method	Gamma irradiation	Gamma irradiation

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 to have an efficiency > 99.995% efficiency against 0.3 µm particles.

In testing, the subject device has demonstrated a level of particulates by 1.1 particles of 0.5 µm/f³.

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
- IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

Summary of clinical testing

Clinical tests have been carried out for surgical procedures such as ophthalmology, orthopedics and neurosurgery. Measurements where made near the surgical site and over the instruments where the results demonstrated a statistically significant reduction in CFU levels.

The clinical tests include 302 CFU measurements from 82 patients in Swedish Hospitals. For the predicate device Operio for ophthalmic surgery the mean CFU value is 0.4 CFU/m^3 and the subject device Operio with additional claims show for orthopaedic surgery a mean CFU value of 0.52 CFU/m^3 and for neurosurgery a mean CFU value of 2 CFU/m^3.

Since CFU level doesn't exceed the predicate device of < 5 CFU it is concluded that substantial equivalence is achieved as clinical validation.

Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K153498).