DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 28, 2017

Surgicube International B.v.
Ger Vijfvinkel
CEO
Seggelant-noord 4
Vierpolders, 3237 MG NL

Re: K163455
Trade/Device Name: Surgicube
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus For A Surgical Operating Room
Regulatory Class: Class II
Product Code: ORC
Dated: August 24, 2017
Received: August 28, 2017

Dear Ger Vijfvinkel:

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

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

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

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

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

Sincerely,

Michael J. Ryan -S

for Tina Kiang, PhD
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)*
K163455

Device Name
SurgiCube®

Indications for Use *(Describe)*

SurgiCube® is a stand-alone device that creates a surgical operating environment with 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 surgical site of the patient is intended to be placed under the air flow which is directed downwards to the surgical site and/or instruments within 32" (80 cm) in length. Device effectiveness may not be reliably detectable at a distance of 32" (80 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Date the summary was prepared is September 25, 2017

The submitter of the 510(k) is:

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Device subject to this 510(k)

Trade name:	SurgiCube®
Common name:	Air handling apparatus for surgery
Classification name	Air-handling apparatus for a surgical operating room
Device class	II
Regulation number	21 CFR 878.5070
Product code	ORC

Predicate device

The legally marketed device to which substantial equivalence

is claimed is: Operio K153498 Cleared 07/20/2016

Device description

The SurgiCube® is an apparatus that provides a localized, optimally HEPA filtered, surgical environment to carry out minimally invasive surgery for ophthalmic procedures. It supplies air around the operating surface using uni directional air flow technique. Possible sources of contamination are sidelined. The patient is physically positioned outside the surgical area; just the operating area is in the field. The surgical team can move around the operating surface without interfering with the air. The uni directional flow together with correct surgical draping create a compact and manageable surgical area that will eliminate airborne contamination risks for patients. The SurgiCube® is equipped with a multiple mechanical filter system, including a High Efficiency Particle Air (HEPA) filter with an efficiency of filtering 99,995% of all particles of 0.3µm.

Indications for use

SurgiCube® is a stand-alone device that creates a surgical operating environment with 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 surgical site of the patient is intended to be placed under the air flow which is directed downwards to the surgical site and/or instruments within 32" (80 cm) in length. Device effectiveness may not be reliably detectable at a distance of 32" (80 cm) from the air flow outlet, and effectiveness depreciates beyond this specified area.

Summary of the technological characteristics compared to the predicate device

SurgiCube® and the predicate device, Operio, have the same intended use and similar technological characteristics.

It is similar in the following way:

- The positioning to the surgical site of the delivery of the air flow is the same.
- The surgical indication, ophthalmic surgery is the same.
- The cleaning efficiency of the HEPA filtered clean air over the surgical site is under 5 CFU for both the subject device (0.12 CFU/ m3) and the predicate device (0.4 CFU/ m3).
- The air flow from the subject device is HEPA-filtered and has the same efficiency (99.995%) to reduce the presence of particulate matter and microorganisms at the surgical site.

It differs in the following way:

- The subject device is not a portable device; it is a stand-alone device.
- The subject device doesn't use a sterile shield in front of the air outlet, instead it uses a single use sterile drape attached onto the side columns.
- The reach of the clean air flow is up to 32" cm from the HEPA filter compared to 47" for the predicate device.
- The delivered air volume to the surgical site for the subject device is 353-777 CFM compared to 235 CFM for the predicate device.

The above stated differences do not introduce any new hazards and test results can confirm that the subject device is as safe and effective for use. In the hazard analysis possible risks have been mitigated that could be associated with the use of the subject device.

Comparison table:

Characteristic	Subject device	Predicate device
	SurgiCube®	Operio K153498
Review Panel	General Hospital	General Hospital
Indications for use	SurgiCube® is a stand-alone device that creates a surgical operating environment with 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 surgical site of the patient is intended to be placed under the air flow which is directed downwards to the surgical site and/or instruments within 32" (80 cm) in length. Device effectiveness may not be reliably detectable at a distance of 32" (80 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	102-150 x 63 x 95 inches	24 x 18 x 47-67 inches
Weight	992 – 1763 lbs	92 lbs
Material	Stainless steel, aluminium and safety glass	Aluminium, powder coated steel, ABS plastic, stainless steel
Electrical Specifications	1. Mains power input: 120 V (AC), 60 Hz 2. Power consumption: 350 VA	1. Mains power input: 120 V (AC), 60 Hz 2. Power consumption: 290 VA
Type of device	Prescription use	Prescription use
Movability	SurgiCube® is a stand-alone 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	Waterproof glass fibre	Nelior membrane media. Folded sheets of nelior.
Air inlet Pre-filter Media	Synthetic fibres and high efficiency water resistant glass fibre	Polyamide mesh
Regular maintenance	HEPA filter to be replaced after 1 year and pre-filters to be replaced after 6 months.	HEPA filter to be replaced after 2000 hours/yearly.
Airflow capacity	SC100: 353 CFM	Airflow is 235 CFM
	SC180: 636 CFM	
	SC200: 706 CFM	
	SC220: 777 CFM	

Efficiency	Bacteria carrying particles at the surgical site is < 0.12 CFU/ m^3	Bacteria carrying particles at the surgical site is 0.4 CFU/m3.
Airflow speed	0.45 m/s	0.4 m/s
Air volume delivered to incision in CFM	SC100: 353 CFM SC180: 636 CFM SC200: 706 CFM SC220: 777 CFM	Airflow over surgical site is 235 CFM
Measured average particulate density at surgical incision	18 particulates of 0.5 µm/f^3 (666/m^3)	1.1 particulate of 0.5 µm/f^3
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 drape	Single-use sterile shield
Sterility Assurance (SAL) for sterile drape	10^{-6} SAL	10^{-6} SAL
Sterilization Method for sterile drape	ETO	Gamma irradiation

Summary of Testing

SurgiCube® fulfils and has been tested against the electromagnetic compatibility requirements. An electromagnetic compatibility test has been carried out at an accredited test laboratory. The report indicates that the SurgiCube® complies to the FCC regulation and 47 CFR 15.
The relevant clauses for electrical safety were tested to confirm that the SurgiCube® complies with the relevant electrical requirements of IEC 60601-1 to ensure that no hazardous situation can occur for the patient. The test results have been presented in the submission.

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, Turbulence tests and Air cleaning efficiency in ambient area to demonstrate air flow and efficiency.

The bench tests demonstrate that SurgiCube® met all performance and acceptance criteria, and does not introduce considerations for safety and efficacy.

Summary of clinical testing

Clinical tests with 26 patients were carried out at ophthalmic procedures. 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. Air viables and particles were measured in order to determine the cleanliness of the clean air area at the surgical site and the instrument site when the SurgiCube® was used for air filtering on patients.

The analysis of the data revealed that it is possible to state at a 95% confidence level that

1. The average number of air viables is with 0.12 CFU/m^3 well below 5 CFU/m^3
2. The average number of particles with a size of ≥0.5 µm is with 666 per m^3 well below 3520 per m^3
3. A significant improvement is achieved when comparing the values inside the Surgicube® with the values outside the Surgicube®:

a. Approximately 470 times less particles of ≥0.5 µm per m^3 (313 821 in background vs. 666 inside Surgicube) and approximately 725 times less particles of ≥5.0 µm per m^3 (1952 in background vs. 2.69 in Surgicube)
b. More than 126 times less CFU per m^3 (15.19 in background vs. 0.12 inside Surgicube)

Conclusion

Based on a comparison of the performance characteristics, the tests performed, clinical and non-clinical, it is concluded that the subject device SurgiCube® is substantially equivalent to the predicate device.