May 4, 2020

Alesi Surgical Ltd.
℅ Michele Lucey
Regulatory Affairs Advisor
Lakeshore Medical Device Consulting LLC
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K200035
Trade/Device Name: Ultravision Visual Field Clearing System
Regulation Number: 21 CFR 878.5050
Regulation Name: Surgical Smoke Precipitator
Regulatory Class: Class II
Product Code: PQM
Dated: January 31, 2020
Received: February 4, 2020

Dear Michele Lucey:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth F. Claverie, MS
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200035

Device Name

Ultravision™ Visual Field Clearing System

Indications for Use *(Describe)*

The Ultravision™ Visual Field Clearing System is indicated for the clearance of smoke and other particulate matter that is created during surgery, including laparoscopic surgery.

The Ultravision™ 5mm Trocar component establishes a path of entry for instruments used in laparoscopic surgery.

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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K200035 510(K)
SUMMARY
TRADITIONAL
As required by 21 CFR 807.92

Submitter Information:

Submitter's Name:	Alesi Surgical Ltd
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Telephone:	603-748-1374

Date Prepared:	4th May 2020
Device Trade Name:	Ultravision™ Visual Field Clearing System
Common Name	Surgical Smoke Precipitator
Classification Name:	21CFR 878.5050
Regulatory Class:	Class II
Product Code(s):	PQM
Predicate Device:	Ultravision™ Visual Field Clearing System (K182053)
Reference Devices:	1. Smoke Evacuator pencil system comprising of Valley Lab Button switch pencil E2516H (K914400) fitted with a Buffalo Penadapt tubing set (PA 2010) (K000904) and Medtronic Rapidvac smoke evacuation generator (K142335) 2. Medcare Yankauer Suction device (K954869)

Indications for Use:

The Ultravision™ Visual Field Clearing System is indicated for the clearance of smoke and other particulate matter that is created during surgery, including laparoscopic surgery. The Ultravision™ 5mm Trocar component establishes a path of entry for instruments used in laparoscopic surgery.

Device Description:

The Ultravision™ Visual Clearing System removes surgical smoke and particulates from the visual field by means of electrostatic precipitation.

The System consists of the Ultravision Generator, the Ionwand Sterile Pack, and the Ultravision 5mm Trocar. The Ionwand is connected to the energy source and is then introduced into the body cavity near the smoke generating electrosurgical device. The Ultravision™ 5mm Trocar is intended for use only with the Ultravision™ Visual Field Clearing System to introduce the Ionwand while providing a pathway for laparoscopic instruments through one 5 mm trocar incision. The trocar may be used with or without the Ionwand component of the system. The system is powered using a rechargeable battery or through mains power. Accessories include the rechargeable battery, battery recharging station, mains converter power supply, mains converter, power supply unit, and patient return adaptor.

The purpose of this submission is to add a new indication for use in open surgical procedures.

Technological Characteristics Comparison Table:

Shown below is a comparison of the subject device with the predicate device.

Comparison Chart			
Feature/ Specification	**DEVICE NAME** Ultravision™ Visual Field Clearing System	**PREDICATE DEVICE** Ultravision™ Visual Field Clearing System	**Comparison**
Regulatory Clearance/ Approval Reference	K200035	K182053	N/A
Product Code	PQM	PQM	Same
Regulation Number	21 CFR 878.5050	21 CFR 878.5050	Same
Regulation Name	Surgical Smoke Precipitator	Surgical Smoke Precipitator	Same
Mechanism of Action	Electrostatic precipitation	Electrostatic precipitation	Same
Where used (environment)	Operating Room	Operating Room	Same
Anatomical Sites	General and laparoscopic procedures	Abdominal sites - laparoscopic procedures	Similar

Comparison Chart			
Feature/ Specification	**DEVICE NAME** Ultravision™ Visual Field Clearing System	**PREDICATE DEVICE** Ultravision™ Visual Field Clearing System	**Comparison**
Intended Use	The Ultravision™ Visual Field Clearing System is indicated for the clearance of smoke and other particulate matter that is created during surgery, including laparoscopic surgery The Ultravision™ 5mm Trocar component establishes a path of entry for instruments used in laparoscopic surgery.	The Ultravision™ Visual Field Clearing System is indicated for the clearance of smoke and other particulate matter that is created during laparoscopic surgery. The Ultravision™ 5mm Trocar component establishes a path of entry for instruments used in laparoscopic surgery.	Similar
Software	Yes – identical to predicate	Yes	Same
Alarms	Yes – identical to predicate	Yes	Same
Accessories	Yes, identical to predicate	Yes	Same
Dimensions	Identical	Identical	Same
Materials	Identical	Identical	Same
Generator Output	9.8KV dc (No Change)	9.8KV dc (No Change)	Same
How Supplied	Non-sterile generator. Sterile Consumable (Ionwand) Non-sterile accessories. Identical	Non-sterile generator. Sterile Consumable (Ionwand) Non-sterile accessories. Identical	Same
Biocompatibility	Meets ISO 10993 Part 5,10 and 11	Meets ISO 10993 Part 5,10 and 11	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Level	10^{-6}	10^{-6}	Same

Summary of Non-clinical Testing:

The system has been previously updated for mains power (K182053) and accordingly new electrical safety and electromagnetic compatibility tests have been successfully completed.

There are no changes to the materials and processing of patient contact materials from the submissions in DEN150022 and K170178, consequently no additional biocompatibility testing is required.

Tests carried out to support the added indication for use in open surgical procedures includes the following:

Name of the Test	Purpose	Acceptance Criteria	Results
Cytotoxicity ISO 10993-5	To analyze the potential of the test article to induce a cytotoxic effect	Must not cause cell lysis or toxicity greater than a grade of 2 (mild reactivity)	Reactivity of grade 1 was observed – Pass
Intracutaneous Irritation ISO 10993-10	To analyze the potential of the test article to induce a local irritation response	No evidence of significant intracutaneous irritation	No evidence of intracutaneous irritation - Pass
Systemic Toxicity ISO 10993-11	To analyze the potential of the test article to induce a systemic response	No evidence of significant systemic toxicity or mortality after test article extracts injection	No evidence of systemic toxicity – Pass
Maximization Sensitization ISO 10993-10	To analyze the potential of the test article to induce a sensitization or allergic response	No evidence of induced delayed sensitization	Not a sensitizer - Pass
Performance Test 1 Simulated Use	Comparison of smoke clearing characteristics of Ultravision versus other smoke clearing devices	Must be considered at least equivalent to comparators	Results of the evaluation demonstrated that Ultravision was at least equivalent to the comparator devices - Pass
Performance Test 2 Risk Assessment comparing the risks associated with open procedure use versus laparoscopic use	Evaluation of device use in an oxygen rich (open) environment considering ozone generation, and tissue damage, includes empirical testing on ozone generation	The risks associated with the use of Ultravision in an open procedure must not be greater than those for a laparoscopic procedure. Ozone generation must comply with 21 CFR Part 801.415.	There were no new risks associated with the use of Ultravision in an open procedure; risks were found to be lower. The time weighted average for ozone production was below acceptable limits - Pass

Performance Test 1

A comparison study was conducted under simulated use conditions to demonstrate that the Ultravision Visual Field Clearing System when used in open procedures provides equivalent performance when compared to the reference device. To support this, a human factors evaluation was also conducted during simulated surgery by actual users (surgeons). The users compared the Ultravision device to an electrosurgical pencil equipped with suction tubing and provided feedback comparing the Ultravision to a hand-held suction device (reference devices).

It was concluded from this feedback that in terms of surgical workflow, ease of use and risks, that the Ultravision system was considered equivalent to the reference device.

Performance Test 2

It was recognized that a potential risk of the system being used in an oxygen rich (open) environment might be the production of ozone. Accordingly, the level of ozone generation in a worst-case model was analyzed. Risk assessment was performed to address the expected relative levels of tissue damage and injury when moving from the original cleared laparoscopic environment to the proposed open environment. This was assessed over six attributes namely, principle of operation, Ultravision Settings, Ultravision components to be utilized to clear surgical smoke, surgical technique, principal electrosurgical modalities used with Ultravision and finally the volumes and composition of smoke produced by electrosurgical devices to be used with Ultravision. This concluded that the risk from open surgery was lower than that associated with the use of Ultravision in its current cleared laparoscopic indication.

Conclusion

Based on a review of bench top assessments, comparison of the device classification, intended use, operating principle, technological characteristics, sterility, and biocompatibility the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K182053.