October 31, 2023

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

Re: K231238
Trade/Device Name: Ultravision2™ System
Regulation Number: 21 CFR 878.5050
Regulation Name: Surgical Smoke Precipitator
Regulatory Class: Class II
Product Code: PQM
Dated: September 25, 2023
Received: September 28, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical

and Infection Control Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
k231238

Device Name
Ultravision2™ System

Indications for Use *(Describe)*
The Ultravision2™ System is indicated for the clearance of smoke and other particulate matter that is created during laparoscopic surgery.

The Ultravision2™ 5mm Trocar component establishes a path of entry for instruments used in laparoscopic surgery.

The Ultravision2™ Generator interfaces directly with the electrosurgical generator and serves as a pass-through for RF energy to RF electrosurgical instruments.

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.

K231238

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

Submitter Information:

Submitter's Name:	Alesi Surgical Ltd
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Contact Person:	Michele Lucey
	Lakeshore Medical Device Consulting LLC.
	128 Blye Hill Landing.
	Newbury,
	New Hampshire 03255
Telephone:	603-748-1374
Date Prepared:	October 31, 2023
Device Proprietary Name:	Ultravision2™ System
Common Name:	Surgical Smoke Precipitator
Classification Name:	Surgical Smoke Precipitator
Classification Regulation:	21 CFR 878.5050
Regulatory Class:	Class II
Product Code(s):	PQM
Predicate Device:	Ultravision™ Visual Field Clearing System (K200035)

Indications for Use:

The Ultravision2™ System is indicated for the clearance of smoke and other particulate matter that is created during laparoscopic surgery.

The Ultravision2™ 5mm Trocar component establishes a path of entry for instruments used in laparoscopic surgery.

The Ultravision2™ Generator interfaces directly with the electrosurgical generator and serves as a pass-through for RF energy to RF electrosurgical instruments.

Device Description/Technological Characteristics:

The Ultravision2™ System is a multifunctional system that synchronizes visual field clearing with the activation of smoke-producing electrosurgical devices. The system interfaces with commercially available electrosurgical instruments. The Ultravision2™ Generator connects directly to a commercially available electrosurgical generator (ESU) and passes the RF energy through to the desired electrosurgical instrument connected to the Utravision2™ Generator. The Ultravison2™ System is able to automate the activation of the Ionwand for visual field clearing to the activation of the electrosurgical device to synchronize visual field clearing with the generation of smoke. The Ionwand™ pack comprises a dedicated percutaneous 3mm trocar/catheter which accommodates the Ionwand™ cable that delivers low energy from the generator to the patient. The Ultravision™ 5mm Trocar includes a dedicated Ionwand™ cable. This device is for prescription use only.

The components of the system are described as follows:

Model #	**Component Description**
DPD-006-001	Ultravision2™ System, including: • Standalone generator • Link cables (x4) • Equipotential cable • Power cable
DAD-001-003	Ionwand Pack, including: • Stainless steel active cable the "Ionwand™" • Trocar/catheter assembly
DAD-003-013	Ultravision 5mm Trocar, including: • 5mm trocar • Ionwand cable assembly

Technological Characteristics Comparison:

The comparison table below provides the similarities and differences between the predicate and subject devices. The modifications made to the subject device do not raise any risk to safety or effectiveness.

Technological Characteristics Comparison Table

Feature/ Specification	Ultravision2™ System	Ultravision™ Visual Field Clearing System	Comparison
Regulatory Clearance/ Approval Reference	K231238 Subject Device	K200035 Predicate Device	N/A
Product Code(s)	PQM	PQM	Equivalent
Regulation Number(s)	21 CFR 878.5050	21 CFR 878.5050	Equivalent
Regulation Name(s)	Surgical Smoke Precipitator	Surgical Smoke Precipitator	Equivalent
Where used (environment)	Operating Room	Operating Room	Equivalent
Anatomical Sites	Abdominal and pelvic cavity	Abdominal and pelvic cavity.	Equivalent
Target population	General patients requiring electrosurgery in a hospital setting	General patients requiring electrosurgery in a hospital setting	Equivalent
Mechanism of Action for Visual Field Clearing	Electrostatic precipitation of smoke to clear the visual field during laparoscopic surgical procedures	Electrostatic precipitation of smoke to clear the visual field during laparoscopic surgical procedures	Equivalent
Generator output Smoke Precipitation	9.8KV dc	9.8KV dc	Equivalent
Current	Ionwand- intermittent max 20µA	Continuous max 10µA	Similar This difference does not raise new questions of safety and effectiveness., confirmed by electrical safety testing
Ionwand tip material	Implant grade Stainless steel, annealed	Implant grade Stainless steel, annealed.	Equivalent
Ionwand tip exposed length	4.0mm	4.0mm	Equivalent
Ionwand insulation wall thickness	0.7mm	0.7mm	Equivalent
Plug and cable length	2.5mm	2.5mm	Equivalent
Ionwand energy modality	HVDC	HVDC	Equivalent
Ionwand working length	109mm	109mm	Equivalent
Mechanism of action of visual field clearance	Electrostatic precipitation	Electrostatic precipitation	Equivalent
Generator smoke clearing activation.	Automatic on/off timed output triggered by energy detection or user selection (manual button press on generator)	Continuous output until switched off on generator	Different, results in less activation of the Ionwand during the procedure. This difference does not raise new questions about safety and effectiveness

Feature/ Specification	Ultravision2™ System	Ultravision™ Visual Field Clearing System	Comparison
Generator Compatibility to Electrosurgical Energy Input	Commercially available Electrosurgical generators, Monopolar, and Bipolar energy input	NA	Compatibility and electrical safety is shown through performance testing. This difference does not raise new questions about safety and effectiveness.
Generator Compatibility to Handpiece	Universal compatibility for monopolar and bipolar energy types	NA	Compatibility is shown through safety and performance testing. This difference does not raise new questions about safety and effectiveness.
5mm Ionwand trocar material	Thermoplastic	Thermoplastic	Equivalent
Retention features	Ribbed	Micro- ridges	Different, results in improved retention of the trocar during the procedure. This difference does not raise new questions about safety and effectiveness
Type of sealing employed	Duckbill valve and separate seal	Duckbill valve and separate seal	Equivalent
Valve and seal material	Elastomer	Elastomer	Equivalent
Software Controls	Software is not a risk control. Provides an audio-visual indication if the Ionwand is touching tissue or a metallic instrument (output is timed with a predetermined shut-off therefore this is not considered to be an alarm)	Software is a risk control providing an audio-visual alarm if the Ionwand is touching tissue or a metallic instrument (required as the output is continuous once manually turned on at the generator)	Different, UV2 has a predetermined timed output which is controlled by hardware only. Thus, software has no role in energy output and is not considered to be a risk control. This difference does not raise new questions of safety and effectiveness.
Software Safety Classification/Level of Concern	Minor Level of Concern (Basic documentation) Class A per IEC 62304	Moderate Level of Concern (Category 2) Class B per IEC 62304	Different, the reduction in safety concerns compared to the predicate does not raise new questions of safety and effectiveness
Applicable Electrical Safety Standards	IEC 60601-1 ISO 60601-1-6 IEC 60601-2-2	IEC 60601-1 ISO 60601-1-6 IEC 60601-2-2	Equivalent
Applicable Electromagnetic Compatibility Standards	IEC 60601-1-2	IEC 60601-1-2	Equivalent
Applicable Software Standards	IEC 62304	IEC 62304	Equivalent

Feature/ Specification	Ultravision2™ System	Ultravision™ Visual Field Clearing System	Comparison
Biocompatibility	Meets ISO 10993	Meets ISO 10993	Equivalent
Sterilization	EtO, validated per ISO 11135	EtO, validated per ISO 11135	Equivalent
Sterility Assurance Level	10^{-6}	10^{-6}	Equivalent
How Supplied (single use)	Ionwand and trocar - supplied sterile in single blister pack or pouch	Ionwand, trocar -supplied sterile in single blister or pouch	Equivalent

Summary of Non-clinical Testing:

Testing demonstrated acceptable device performance for the device's intended use. System and software verification and validation activities were successfully completed.

Test Performed	Standard Followed	Acceptance Criteria	Test Results
Shelf life	ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Medical Device Packages ASTM 2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration ASTM F88/F88M -15 Standard Test Method for Seal Strength of Flexible Barrier Materials	Product and package must demonstrate stability for the claimed shelf life of 5 years.	Pass
Software verification and validation	IEC62304 2006+A1:2015 Medical Device Software – Software Life Cycle Process	Device functions controlled by software must perform as intended	Pass
Electrical safety and electromagnetic compatibility	IEC 60601-1 Medical Electrical Equipment, Edition 3.1, which is Edition 3.0 (2005-12) as modified by AM1 (2012-07) evaluation. IEC 60601-2-2 High Frequency Surgical Equipment (2017-03) evaluation EN 60601-1-2:2015 + A1:2021 Medical electrical equipment General	Device must meet the requirements of the applicable clauses in the standards	Pass

Test Performed	Standard Followed	Acceptance Criteria	Test Results
	requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances		
Dimensional and physical verification of unit	NA	Device must meet dimensional specification and physical specifications as per internal standards.	Pass
High voltage output	NA	Device must deliver specified output, into required loads, at given temperatures and humidities, and for the specified product lifetime as per internal standards.	Pass
Generator basic function including:	NA	Device must meet specifications for connections and functionality as per internal standards.	Pass
Generator safety measures including:			
Generator user interface hardware control	NA	Must meet specifications for device function independent of software, extreme misuse, or single fault conditions as per internal standards.	Pass
Generator high voltage power management	NA	Must meet specifications for DC output under proximity and HVDC limit protection measure as per internal standards.	Pass
Generator surgical energy detection	NA	Device must demonstrate energy detection for external ultrasonic energy as per internal standards.	Pass
Mechanical connections and controls	NA	Device must demonstrate acceptable durability of link cables, fascia connections, and cable retention as per internal standards.	Pass
Surgical generator compatibility	NA	Device must demonstrate compatibility with applicable generators in terms of load curve characterization, CQM performance, HF leakage, and RF detection. as per internal standards.	Pass
Design validation under simulated use conditions	NA	Must demonstrate that the device can achieve its intended use when used by end users as per internal standards.	Pass

Biocompatibility

The tissue contacting components of the Ultravision2™ System are identical in material and process to the previously cleared devices. No additional biocompatibility testing was performed.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in this 510(k) submission, K231238 is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200035, Class II (21 CFR 878.5050), product code PQM.