DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 26, 2017

Alesi Surgical Ltd.
David Broderick
Quality & Regulatory Manager
Cardiff Medicentre, Heath Park
Cardiff, CF14 4UJ GB

Re: K170178
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: April 26, 2017
Received: May 1, 2017

Dear David Broderick:

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,

Lori A. Wiggins -S6

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

DEPARTMOF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB N -0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170178

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 laparoscopic surgery.

The Ultravision 5mm Trocar component also 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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SECTION 6

510(K) SUMMARY

510(K) SUMMARY
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: **19th May 2017**

Device Trade Name: Ultravision™ Visual Field Clearing System

Classification: Class II

Product Code(s): PQM

Regulation Number(s): 878.5050

Predicate Devices: Ultravision™ Visual Field Clearing System DEN150022

Intended Use: 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 also establishes a path of entry for instruments used in laparoscopic surgery.

Device Description: The Ultravision™ Visual Clearing System removes surgical smoke from the visual field during laparoscopic surgery by means of electrostatic precipitation. The System consists of the Ultravision Generator, the Ionwand Sterile Pack, and the Ionwand 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 a new accessory device 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 Ultravision™ 5mm Trocar provides an alternative to the currently available Ultravision™ Visual Field Clearing System Ionwand™ Sterile Pack for introduction of the Ionwand. The Ultravision™ 5mm Trocar is a standard dilating laparoscopic trocar compatible for use with 5mm instruments. The trocar design includes a discrete lumen that is positioned separate from the main trocar channel and which accepts the Ionwand component of the system. The trocar design allows the distal tip of the Ionwand to exit the trocar some 12mm from its distal point and at an angle to the trocar body that positions the Ionwand at a point close to but not interfering with the 5mm energy instruments that are intended to be accommodated by the trocar. The Ultravision™ 5mm trocar and Ionwand are provided packaged together in the same sterile barrier packaging. The trocar may be used with or without the Ionwand component of the system.

Nonclinical testing:

The equivalence of the Ultravision 5mm Trocar to the predicate devices has been though the following tests and assessments:

Test	Description	Results
Performance of the system to clear the visual field of smoke and particulate matter	Performance comparison to the predicate device under simulated use conditions	Equivalent to predicate - Pass
Usability	Complexity of use compared to the predicate and reference device	Equivalent to predicate and reference - Pass
Ionwand removal and reinsertion	Repeated insertions/removals performed and forces both quantitative and qualitative evaluations performed	Equivalent to predicate and reference - Pass
Leak resistance and sealing, maintenance of pneumoperitoneum during use	Pressure tests under high and low pressures with and without instruments or Ionwand inserted, including multiple cycles of use	Equivalent to predicate or reference - Pass
Strength, resistance to bending	Tensile or pressure forces applied to shaft, trocar, and connections	Equivalent to predicate or reference - Pass

Dimensional Verification	Confirmation of dimensional characteristics by dimensional evaluation	Pass
Luer fitting	Confirmation of compliance with industry standard luer fitting	Pass
Electrical Safety	Dielectric breakdown, radio-frequency applied parts, capacitive coupling	Pass
Biocompatibility per ISO 10993	Appropriate biocompatibility based on tissue contact and duration	Pass
Sterilization and shelf life studies	Validated sterilization cycle according to industry standard, shelf life studies on accelerated aging conditions including product and package evaluations	Pass

The results of the testing demonstrated acceptable performance for the device and substantial equivalence to the predicate device.

Summary of Technological Characteristics Demonstrating Substantial Equivalence:

Feature/ Specification	Ultravision™ Visual Field Clearing System Subject Device	Ultravision™ Visual Field Clearing System Primary Predicate Device	Ethicon Endopath Excel Bladeless Trocar with Stability Sleeve 5 - 12mm Reference Device	Comparison
Regulatory Clearance/	Pending	DEN150022	K032676	N/A
Product Code	PQM	PQM	GCJ	N/A
Regulation Number	878.5050	878.5050	876.1500	Equivalent
Regulation Name	Surgical Smoke Precipitator	Surgical Smoke Precipitator	Endoscopes and Accessories.	Equivalent
Where used (environment)	Laparoscopic surgery	Laparoscopic surgery	Abdominal, thoracic and gynecological minimally invasive procedures	Equivalent (laparoscopic surgery includes all the predicate anatomical sites)
Anatomical Sites	Abdominal and gynecological minimally invasive procedures	Abdominal and gynecological minimally invasive procedures	As above	Equivalent
Trocar type	Blunt trocar with dilating tip	N/A	Blunt trocar with dilating tip	Equivalent
Trocar material	Thermoplastic	N/A	Thermoplastic	Equivalent
Retention features	Micro- ridges	N/A	Ridges	Similar feature but different dimension with no impact on performance or safety
Type of sealing employed	Duckbill valve and separate seal	N/A	Duckbill valve and separate seal	Equivalent
Valve and seal material	Elastomer	Elastomer	Elastomer	Equivalent

Feature/ Specification	Ultravision™ Visual Field Clearing System Subject Device	Ultravision™ Visual Field Clearing System Primary Predicate Device	Ethicon Endopath Excel Bladeless Trocar with Stability Sleeve 5 - 12mm Reference Device	Comparison
Trocar working length	94mm	N/A	100 / 102mm	Similar feature but different dimension with no impact on performance or safety
Trocar main lumen	5.8mm	N/A	5.95 / 13mm	Similar feature but different dimension with no impact on performance or safety
Trocar O/D	10.0mm	N/A	8.0 / 15.2mm (Covers the range of items from predicate submission)	Similar feature but different dimension with no impact on performance or safety
Ionwand™ working length	129mm	109mm	N/A	Similar feature but different dimension with no impact on performance or safety
Ionwand™ overall diameter	1.4mm	2.0mm	N/A	Similar feature but different dimension with no impact on performance or safety
Ionwand™ tip material	Implant grade Stainless steel. annealed	Implant grade Stainless steel, annealed.	N/A	Equivalent
Ionwand™ tip, exposed length	4.0mm	4.0mm	N/A	Equivalent
Ionwand™ insulation wall thickness	0.4mm	0.7mm	N/A	Similar feature but different dimension with no impact on performance or safety
Plug and cable length	2.5mm	2.5mm	N/A	Equivalent
Generator	Ultravision™ generator (fixed power output)	Ultravision™ generator (fixed power output)	N/A	Equivalent
How Supplied	Supplied sterile in single pouches	Supplied sterile in single blister	Supplied sterile in single pouches	Equivalent

Feature/ Specification	Ultravision™ Visual Field Clearing System Subject Device	Ultravision™ Visual Field Clearing System Primary Predicate Device	Ethicon Endopath Excel Bladeless Trocar with Stability Sleeve 5 - 12mm Reference Device	Comparison
Biocompatibility	Meets ISO 10993 Part 5,10 and 11	Meets ISO 10993 Part 5,10 and 11	Unknown	Assume predicate is biocompatible since it is an approved device
Sterilization	EtO	EtO	Gamma Irradiation	Similar feature but different dimension with no impact on performance or safety
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	Assume predicate has the standard sterility assurance level since it is an approved device

Conclusion:

The subject device is substantially equivalent to the predicate device.