DE NOVO CLASSIFICATION REQUEST FOR ULTRAVISION™ VISUAL FIELD CLEARING SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Surgical smoke precipitator: A surgical smoke precipitator is a prescription device intended for clearance of the visual field by precipitation of surgical smoke and other aerosolized particulate matter created during laparoscopic surgery.

NEW REGULATION NUMBER: 21 CFR 878.5050

CLASSIFICATION: CLASS II

PRODUCT CODE: PQM

BACKGROUND

DEVICE NAME: ULTRAVISION™ VISUAL FIELD CLEARING SYSTEM

SUBMISSION NUMBER: DEN150022

DATE OF DE NOVO: May 26, 2015

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INDICATIONS FOR USE

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

LIMITATIONS

The sale, distribution, and use of the device are restricted to prescription use in accordance with 21 CFR §801.109.

The Ultravision™ Visual Field Clearing System is not intended for non-laparoscopic surgeries. The provided nonclinical and clinical studies did not address open surgeries of any kind.

The Ultravision™ Visual Field Clearing System should only be used by appropriately trained medical personnel.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Ultravision™ Visual Field Clearing System is a device that precipitates surgical smoke generated during laparoscopic procedures to clear the visual field. The device components are summarized briefly in Table 1, below.

Table 1 – Device Components

Components of the Ultravision™ Visual Field Clearing System		
Model #	***Component Description***	***Purpose***
DAD-001-010	Standalone, battery-operated generator	Generation of energy source
DAD-001-024	Battery recharging station	Recharging of the reusable battery
DAD-001-003	Ionwand™ Sterile Pack consisting of Stainless steel active cable; the Ionwand™, Catheter and Trocar	Ionwand™: Delivery of the energy from the generator to the abdominal cavity. Catheter: Holds Ionwand™ in place during surgery Trocar: Introduction of the catheter into the abdominal cavity
DAD-001-006 (Solid) DAD-001-007 (Split)	Patient return adaptor	Provides common return path with electrosurgical generator

The standalone battery-operated generator unit is used to generate the energy source that is responsible for the electrostatic precipitation of smoke particles.

The Ionwand™ (Figure 1) is an active cable that terminates in filaments of medical grade stainless steel. The Ionwand™ is introduced into the abdomen of the patient and provides the source of the electrons that create the negative ions that transiently charge the surgical smoke particles. The Ionwand™ is held in place during the surgical procedure using a catheter. The catheter is introduced into the abdominal cavity using a laparoscopic trocar (Figure 2). The Ionwand™ and the preassembled catheter and trocar are supplied sterile together in one single-use disposable package (Figure 3). The catheter, trocar and Ionwand™ constitute the only tissue contacting components of the device.

Figure 1 – Ultravision™ Visual Field Clearing System Component: Ionwand™

Figure 2 – Ultravision™ Visual Field Clearing System Components: Catheter and Trocar.

Figure 3 – Packaged Sterile Ultravision™ Visual Field Clearing System Components: Ionwand™, Catheter and Trocar.

Reusable patient return adaptor ("PRA"). The Ultravision™ Visual Field Clearing System has been designed to operate with both instruments that require a patient return electrode (i.e., monopolar instruments) and those that do not (i.e., bipolar and ultrasonic instruments). To function, the Ultravision™ Visual Field Clearing System requires the use of a patient return electrode (not supplied). The PRA is only required when using a monopolar instrument. The PRA connects the Ultravision™ generator to the electrosurgical unit with which it is used, allowing both generators to share a common patient return pad. There are two variants of the

PRA; one to receive a "solid" patient return electrode connector and a second that receives a "split" patient return electrode connector.

BIOCOMPATIBILITY/MATERIALS

Biocompatibility testing was conducted on the Ultravision™ Visual Field Clearing System's patient-contacting components, as described in Table 3, below.

Table 2 – Biocompatibility Testing

Test	Purpose	Method	Result
In vitro Cytotoxicity	Determine if the Ionwand™, catheter, and trocar elicit cytotoxic responses	ISO 10993-5:2009 Biological Evaluation of Medical Devices: Tests for Cytotoxicity: in Vitro b(4) CCI :	Negative control b(4) : 0 Positive control b(4) : 4 Test article: Grade 1 (mild reactivity). PASS
Sensitization	Evaluate the potential for delayed dermal contact sensitization of the Ionwand™, catheter, and trocar	ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10 (2010): Tests for Irritation and Skin Sensitization: Maximization test.	Scores of 0 for all negative control and test samples. (PASS)
Intracutaneous Reactivity	Determine whether extracts from the Ionwand™, catheter, and trocar will be irritating to the dermal tissue of the rabbit	ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10 (2010): Tests for Irritation and Skin Sensitization: Maximization test.	Pass
Acute Systemic Toxicity	Evaluate acute systemic toxicity of the test article extract following a single intravenous or intraperitoneal injection in mouse	ISO 10993 standard- Part 11 (2006): Tests for Systemic Toxicity	Pass: No mortality during the study in mice injected with the test article extracts. All animals appeared clinically normal at the beginning and throughout the study
Endotoxin Levels	Detect and quantify bacterial endotoxin in the Ionwand™, catheter and trocar	ANSI/AAMI ST72:2011: Bacterial endotoxin -Test methods, routine monitoring and alternatives to batch testing	b(4) EU/device PASS

CHEMICAL CHARACTERIZATION OF TREATED SMOKE/RISK ASSESSMENT:

The purpose of this study was to assess potential chemical modifications and new chemical species resulting from Ultravision™ Visual Field Clearing System treatment of surgical smoke with the intention to identify and quantify any newly generated chemical species or confirm a lack of observable modifications to surgical smoke. Surgical smoke was generated in a simulated pneumoperitoneum using monopolar and ultrasonic tools. Surgical smoke was characterized using b(4) CCI Mass Spectrometry, b(4) CCI Mass Spectrometry, b(4) CCI X-ray and b(4) CCI b(4) CCI Spectroscopy. No measureable chemical modifications to surgical smoke were observed following treatment of surgical smoke.

A risk assessment was conducted to address the effects of the use of the Ultravision ™ Visual Field Clearing System on surgical smoke. As the chemical characterization did not result in identified chemical changes, the risk assessment addressed the precipitation of surgical smoke against the amount of surgical smoke that would be retained in the surgical

site with the current practices of dilution and purging of surgical smoke. The risk assessment addresses acute irritancy and tolerance; system acute toxicity, local chronic tolerances; distributed chronic toxicity; and distributed and local carcinogenicity and mutagenicity. The risk assessment concludes that the additional amount of surgical smoke (1-40%) that is likely to remain in the patient does not introduce any new risk to the patient beyond the current standard of care.

The provided chemical characterization and risk assessment support the conclusion that the use of the Ultravision™ Visual Field Clearing System does not create new safety concerns in the precipitation of surgical smoke.

SHELF LIFE/STERILITY

The sterilization process for the Ultravision™ Ionwand™ sterile package, which includes the Ionwand™, Catheter, and Trocar, has been validated in accordance with the requirements of the standard ISO 11135-1:2007, "Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices." The b(4) CCI method was used, and the sterility assurance level was 1×10^{-6}.

The ethylene oxide and ethylene chlorohydrin residuals remaining on the device after sterilization and 7 days of aeration are below the limits described in the ANSI AAMI ISO 10993-7:2008(R)2012 for a limited exposure device.

The sterile components of the Ultravision™ Visual Field Clearing System (the Ionwand™, catheter and trocar) are packaged in custom designed b(4) blister trays with b(4) lids under ISO b(4) CCI conditions. b(4) CCI The Ultravision™ Generator (x1), Battery (x2), Recharging Station (x1), Patient Return Adaptor (SOLID, x1) and Patient Return Adaptor (SPLIT, x1) are provided non-sterile in a shipper.

Shelf Life: The applicant provided accelerated aging test reports for a three year sterile packaging claim and supporting real time test reports conducted over one year. Package inspections and product performance evaluations were conducted both at baseline and after aging and simulated shipping conditions.

The shelf life testing consisted of the following packaging and functional testing.

Packaging testing:

- Visual inspection of the package for obvious damage, deterioration, or defects
- Package seal strength Dye Penetration Testing

Functional product testing:

- Visual inspection of the product for obvious degradation or damage
- Plug secure connection test

The packaging and functional product testing is sufficient to support the three-year shelf life.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The submission contained test reports for:

- IEC 60601-1:2005 + C:109 + A2:10, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2007: Medical Electrical Equipment - Part 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and Tests

The report utilized a Risk Management process in accordance with: ISO 14971: - Application of risk management to medical devices, to determine the appropriate and applicable test clauses.

IEC 60601-1:
The sponsor addressed the differences in the tests performed versus the US requirements; the subject device passed all applicable requirements for AAMI/ANSI ES60601-1.

- The following tests were completed on the device as a system:
    - Power Input (IEC 60601-1 §4.11)
    - Humidity and Preconditioning (§5.7)
    - Determination of accessible parts (§7.1.2)
    - Markings:
        - Legibility (§7.1.2)
        - Durability (§7.1.3)
    - Voltage limitation (§8.4.4)
    - Means of Protection (§8.5.1)
        - Means of Patient protection (§8.5.1.2)
        - Means of Operator protection (§8.5.1.3)
        - Separation of Patient Connections (§8.5.2)
        - Working voltage measurement (§8.5.4)
        - Defibrillation proof applied parts (§8.5.5)
        - Energy reduction test (§8.5.5.2)
    - Leakage Current test (§8.7)
    - Dielectric Voltage withstand (§8.8.3)
    - Ball pressure (§8.8.4.1)
    - Thermal cycling test for spaces filled by insulating compound (§8.9.3)
    - Stability and Transportability (§9.4.2)
    - Acoustic Energy Measurement (§9.6.2.1)
    - Temperature test (§11)
    - Overflow, Spillage, Leakage, Cleaning, Sterilization and Disinfection, Harmful Ingress of Liquids (§11.6)
    - Abnormal Operation and Single Fault Conditions (§13)
    - Enclosure Mechanical Strength (§15.3)

    - Drop test (§15.3.4)
    - Mould stress relief (§15.3.6)
    - Reverse Battery connection / overcharging (§15.4.3)
- All tests passed.

IEC 60601-2-2:

- The following tests were completed on the device
    - Compatibility with third party Active Electrodes
        - Neutral Electrode cord attachment (§201.15.101.2)
        - Neutral Electrode cord connector, no conductive parts on Patient (§201.15.101.3)
- All tests passed.

IEC 60601-1-2:

- The test report confirms that there were no modifications made to the devices in order to achieve compliance.

- The system encompasses two components that require separate types of testing (battery charging station and the generator unit).
    - These two components work independently of each other and do not need to be tested as a system.

- The following tests were completed of the generator unit:
    - Electromagnetic radiation disturbance(§6.1.1.1)
    - Electrostatic Discharge (ESD) (§6.2.2.1)
    - Radiated RF Electromagnetic Fields (§6.2.3.1)
    - Conducted Disturbances, Induced by RF fields (§6.2.6.1)
    - Power Frequency magnetic fields (§6.2.8.1)
    - All tests passed.

- The following tests were completed of the battery charging station:
    - Electromagnetic radiation disturbance (§6.1.1.1)
        - Mains terminal disturbance
    - Harmonic Distortion (§6.1.3.1.1)
    - Voltage fluctuation and flicker (§6.1.3.1.2)
    - Electrostatic Discharge (ESD) (§6.2.2.1)
    - Radiated RF Electromagnetic Fields (§6.2.3.1)
    - Electrical fast transients and bursts (§6.2.4.1)
    - Surges (§6.2.5.1)
    - Conducted Disturbances, Induced by RF fields (§6.2.6.1)
    - Voltage Dips, short interruptions and voltage variations on power supply input lines (§6.2.7.1)
    - Power Frequency magnetic fields (§6.2.8.1)
    - All tests passed.

SOFTWARE

The first function of the software in the Ultravision™ generator is to generate the audible alerts through the speaker that indicate when the system is in 'proximity alarm' mode – i.e., in contact with tissue or another conductive surface and hence not able to operate at full smoke-clearing efficiency. This is a parallel alert to the visual indicators alongside the Ionwand™ and return sockets on the front of the generator, which are not under software control.

The second function of the software is to illuminate the fault light on the generator upper membrane in the situation where the speaker becomes accidentally disconnected from the main processor board of the generator.

The software is considered to have a moderate level of concern (LOC) because:

1) The software does not control the high potential voltage source. The hardware has built in back-off control.
2) The software only controls audible alarms as detected by the hardware.
3) The audible alarms are additional signals and risk controls to those implemented in hardware.
4) Under any condition where the hardware backs off the high potential source, this would reduce the effectiveness of the device clearing smoke and thus give a clear visual indication of under-performance to the user. This can be diagnosed independent of the audio alarm and resolved by the user.

It appears that the only harm failure the software could cause is ineffective clearing of the surgical smoke.

The applicant has provided adequate software documentation per FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The sponsor has tested its specifications of the alarm both under fault and normal conditions and the software functioned according to specification. Therefore, based on the traceability analysis, all identified hazards are properly mitigated.

PERFORMANCE TESTING – ANIMAL

A safety and simulated use performance validation of the Ultravision™ Visual Field Clearing System was conducted in a GLP animal study. Simulated laparoscopic surgeries (50-100 minutes in duration) were performed on porcine omentum using monopolar, bipolar and ultrasonic electrosurgical instruments, followed by 28 day recovery period. Histology, coagulation and clinical chemistry were evaluated for preoperative, immediate post-operative and 28 day post-operative conditions.

The study had the following objectives:

- Demonstration of the functionality of the Ultravision™ Ionwand™ trocar/ introducer assembly

- Demonstration of the ability of Ultravision™ Visual Field Clearing System to maintain a smoke free laparoscopic surgical field during normal use of monopolar, bipolar and ultrasonic electrosurgical cutting and ablation devices.
- Evaluation on anesthetic control of the subject device.
- Evaluation of effects on pneumoperitoneum
- Verification of alarm if Ionwand™ touches tissue/organs
- Evaluation of effect of device on hematology, clinical chemistry and coagulation

Acceptance criteria for the study were qualitative verification of performance and usability, through observed clearance of the visual field and an absence of observed clinical chemistry or histology concerns.

The results of the study indicated that the device functions as intended without usability concerns and that there were no identified clinical chemistry concerns.

The study was concluded to be adequate to demonstrate performance of the device and supports safe use of the device.

SUMMARY OF CLINICAL INFORMATION

The applicant completed a randomized, double-blinded, controlled, prospective trial consisting of 30 patients with six weeks of follow-up on 25/30 enrolled patients. The 30 patients underwent elective cholecystectomy at a single site with an active device and a de-activated control device to blind the surgeon. The primary endpoint of the study was the maintenance of a clear visual field during surgery. Secondary endpoints included patient safety (based on details of adverse events and bloodstream measurement of carboxyhemoglobin before and after surgery), pain score at discharge, and number of times a procedure was interrupted due to impairment of visual field by presence of particulates or smoke. Additional secondary endpoints were included in the study as potential metrics of device effectiveness, but these metrics were not considered necessary to support granting of this *de novo* request.

All patients in the study had a single-use sterile Ionwand™ placed percutaneously by the surgeon. The Ultravision™ generator was switched on throughout surgery. All surgical procedures were video-recorded using a direct output link from the laparoscopic camera in use to a digital video recorder. Relevant events of note and any problems associated with the use of the Ultravision™ Visual Field Clearing System that occurred during surgery were recorded by an independent member of the research team present.

All patients had a 6-week postoperative visit and assessment by their surgeon. At this visit patients were asked about postoperative pain, nausea, infection and medications taken. Each patient indicated their pain on a 100mm visual analog scale (VAS).

The following results were provided:

Primary Endpoint: The Ultravision™ Visual Field Clearing System was determined to be effective at maintaining a clear visual field during the surgeries. The surgeons and

reviewing panel rated the treatment group to have a higher mean proportion of procedures with effective visibility than the control group.

Secondary Endpoints: There were no adverse events that could be attributed to the device. There was no detectable difference in either Carbon Monoxide (CO) or Methemogloblin (MetHb) levels between the two groups of patients both pre- and post-surgery. Pain scores were similar between treatment and control groups.

Treatment and control groups both had procedure interruptions, but in the treatment group there were eight procedures that had no interruptions. In the control group, no cases were completed without interruptions resulting from impairment of the visual field. The frequency with which the surgeon needed to remove the laparoscopic camera for cleaning was also different between the two groups of patients. In 85% of the procedures during which Ultravision™ Visual Field Clearing System was active, there was no requirement to remove the camera for cleaning. However, in the control group, only 35% of the procedures could be completed without camera cleaning.

This study confirmed safe performance of the device in a clinical setting as demonstrated by the controlled clinical trial, and contributed to the benefit/risk assessment.

Pediatric Extrapolation

In this *de novo* request, existing data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

The labeling is sufficient and meets the requirements of 21 CFR 801.109. The user manual contains the indications for use, summary device description, warnings and precautions, instructions for use, instructions for device maintenance, troubleshooting instructions, shelf life, and information related to electromagnetic compatibility.

RISKS TO HEALTH

Table 4 below identifies the risks to health that may be associated with use of the Surgical smoke precipitator and the measures necessary to mitigate these risks.

Table 4 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measures**
Electrical shock	Electrical safety testing Labeling
Electromagnetic interference with other devices	Electromagnetic compatibility testing Labeling
Infection	Sterilization validation Shelf-life validation Labeling
Adverse tissue reaction	Biocompatibility evaluation

Tissue injury **S**	Animal testing Software verification, validation, and hazard analysis Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the Surgical smoke precipitator is subject to the following special controls:

1. Adverse tissue reaction must be mitigated through the following:
   a. Chemical characterization and toxicological risk assessment of the treated surgical smoke.
   b. Demonstration that the elements of the device that may contact the patient are biocompatible.
2. Electrical safety and electromagnetic compatibility testing must demonstrate that the device performs as intended.
3. Software verification, validation, and hazard analysis must be performed.
4. Performance data must demonstrate the sterility of the patient contacting components of the device.
5. Performance data must support the shelf life of the sterile components of the device by demonstrating continued functionality, sterility and package integrity over the identified shelf life.
6. Animal simulated-use testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:
   a. Device must be demonstrated to be effectively inserted, positioned and removed from the site of use.
   b. Device must be demonstrated to precipitate surgical smoke particulates to clear the visual field for laparoscopic surgeries.
   c. Device must be demonstrated to be non-damaging to the site of use and animal subject.
7. Labeling must identify the following:
   a. Detailed instructions for use.
   b. Electrical safety and electromagnetic compatibility information.
   c. A shelf life.

BENEFIT/RISK DETERMINATION

The risks of the device are based on nonclinical laboratory, animal studies, and the clinical study described above. There were no device-related adverse events during the clinical study. Additionally, there was no detectable difference in either CO or MetHb levels between the two groups of patients both pre- and post-surgery despite greater volume of gas administered in the control group for the 30 patient trial.

The probable benefits of the device are also based on the nonclinical laboratory, animal, and clinical study described above. The probable benefits are:

1. Improved visual field

2. Less gas volume needed for insufflation
3. Less frequent need to stop procedures to clean the camera lens or vent accumulated debris and gas.

The subject device does not directly benefit the patient. However, the device appears to benefit surgeons performing laparoscopic procedures through maintenance of a clear visual field. The use of this device may allow the surgeon to proceed without having to stop procedures to clean the camera lens and/or vent the accumulated debris.

Patient Perspectives

Patient-reported pain scores were recorded for both treatment and control groups in the clinical trial. Pain scores were based on the VAS scale and were similar between both groups.

Benefit/Risk Conclusion

Maintaining a clear visual field is critical during laparoscopic procedures. Use of this device may allow the surgeon to proceed without having to stop procedures to clean the camera lens and/or vent the accumulated debris. No adverse events were attributed to the device in the clinical study.

In conclusion, given the available information above, the data support that for precipitation of surgical smoke for laparoscopic procedures, the probable benefits outweigh the probable risks for the Ultravision™ Visual Field Clearing System. The device provides benefits and the risks can be mitigated by the use of general and the identified special controls.

CONCLUSION

The de novo request for the Ultravision™ Visual Field Clearing System is granted and the device is classified under the following:

Product Code: PQM
Device Type: Surgical smoke precipitator
Class: Class II
Regulation: 21 CFR 878.5050