DE NOVO CLASSIFICATION REQUEST FOR
CLEANCISION™ WOUND RETRACTION AND PROTECTION SYSTEM

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Irrigating Wound Retractor Device:** An irrigating wound retractor device is a prescription device intended to be used by a surgeon to retract the surgical incision, to provide access to the surgical wound, to protect and irrigate the surgical wound, and to serve as a conduit for removal of fluid from the surgical wound.

NEW REGULATION NUMBER: 21 CFR 878.4371

CLASSIFICATION: II

PRODUCT CODE: PQI

BACKGROUND

DEVICE NAME: CleanCision™ Wound Retraction and Protection System

SUBMISSION NUMBER: DEN150038

DATE OF DE NOVO: August 13, 2015

CONTACT: Prescient Surgical
1585 Industrial Road
San Carlos, CA 94040

INDICATIONS FOR USE

The CleanCision™ Wound Retraction and Protection System is intended for use by a surgeon during abdominal surgery to: retract the surgical incision, provide access to the abdominal cavity, and irrigate the surgical wound edge. The device may aid in the prevention of wound edge contamination. This device is intended to deliver a sterile irrigant solution and serve as a conduit for fluid removal from the surgical wound edge.

LIMITATIONS

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

Contraindications

- Use of the CleanCision™ Wound Retraction and Protection System is contraindicated when, in the judgement of the physician, use of this device would be contrary to the best interest of the patient.

Warnings

- This device was designed and tested for single patient use only. Do not reuse, reprocess, or resterilize this device.
- Avoid contact with potential ignition sources. Do not use in the presence of flammable anesthesia.
- Device has been tested with a max hospital suction pressure of 370 mmHg.

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

DEVICE DESCRIPTION

The CleanCision™ Wound Retraction and Protection System (CleanCision™ System) is a sterile, single-use surgical wound retraction and protection device that integrates surgical retraction, wound barrier protection, and controlled fluid delivery and removal, as shown in Figure 1, below. The wound barrier protection component is comprised of a flexible, double-walled sheath with an inner layer that may aid in the prevention of wound edge contamination. The wound retraction component is formed by attaching the sheath to a fixed-diameter ring at the bottom, designed to be inserted into the abdominal cavity, and a radially-adjustable upper retraction ring at the top, designed to remain outside of the body and be actuated to achieve wound retraction. The double-walled sheath also includes integrated fluid delivery and removal. Fluid is delivered via gravitational feed from an external sterile irrigation solution bag into the device and delivered to the wound edges through the permeable outer layer of the sheath. Excess fluid is removed through a separate chamber within the sheath via a connection with the hospital's standard vacuum suction mechanism.

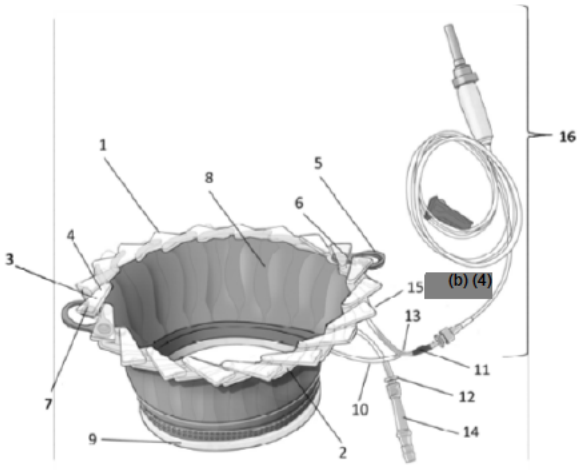

Figure 1. CleanCision™ Wound Retraction and Protection System

Table 1. – CleanCision™ Wound Retraction and Protection System (refer to Figure 1)

SUMMARY OF NONCLINICAL/BENCH STUDIES

The sponsor conducted a series of non-clinical performance testing to demonstrate that the CleanCision™ System would perform as anticipated. Non-clinical testing included: biocompatibility, shelf-life, sterility, package integrity, bench, animal, and usability performance testing.

BIOCOMPATIBILITY/MATERIALS

A. Biocompatibility

The CleanCision™ System is classified as an externally communicating, blood path indirect contact, limited exposure (≤ 24 hours) device. Biocompatibility testing was performed according to ISO 10993-1:2009, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process." Testing was completed on finished devices, (b) (4) sterilization. As summarized in Table 2, the CleanCision™ System was found to be non-cytotoxic, non-sensitizing, non-toxic, non-irritating, non-pyrogenic and non-hemolytic, mitigating the risk of adverse tissue reaction.

Table 2. – Summary of Biocompatibility Testing

Test	Purpose	Methods	Results
Cytotoxicity	Determine the potential biological reactivity of a mammalian cell culture (L929) in response to the test article extract.	ISO 10993-5 – Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity	Non-cytotoxic
Sensitization	Determine the allergenic potential or sensitizing capacity of the test article after extraction with a polar and non-polar solvent.	ISO 10993-10 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Non-sensitizer

Test	Purpose	Methods	Results
Irritation	Determine the potential irritation effects of the test article extraction with a polar and non-polar solvent.	ISO 10993-10 – Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Non - irritant
Acute Systemic Toxicity	Determine the potential toxic effects of the test article extract as a result of a single-dose systemic injection in mice.	ISO 10993-11 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	No acute systemic toxicity response was observed from test article extract.
Particulate Testing	To determine the number of particulates [redacted] and the concentration of particulates from the test article from water injection.	USP <788> Particulate Matters in Injections	Results met USP Limits of ≤ 25 particles per mL for [redacted] particles per mL for [redacted] µm for nominal volumes of [redacted]
Rabbit Pyrogen Test (Material Mediated)	Determine the presence of chemical pyrogens in test article extracts.	ISO 10993-11 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	Non-pyrogenic
Limulus Amebocyte Lysate (LAL) Bacterial Endotoxin Testing	In vitro assay for detection and quantitation of bacterial endotoxin in test article extract.	USP <85> Bacterial Endotoxin Test	Non-pyrogenic
Hemocompatibility (Hemolysis)	Determine the potential hemolytic activity on rabbit blood in response to the test article and to its extract.	ISO 10993-4 – Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood.	Non - hemolytic

B. Extractables and Leachables

Chemical characterization studies were completed per ISO 10993-18: 2005 "Biological evaluation of medical devices -- Part 18: Chemical characterization of materials" to determine the amounts of extracted inorganic and polymer-related organic substances. The extractions of the CleanCision™ System were performed at [redacted] with both polar and non-polar extraction solvents. The chosen conditions represented aggressive worst-case conditions. Results indicate that a total of six chemical compounds from the polar solvent were characterized above the limit of detection. No chemical compounds were observed above the limit of detection in the nonpolar solvent. Subsequently, a toxicological risk assessment was conducted per ISO 10993-17:2002 "Biological evaluation of medical devices -- Part 17: Methods for the establishment of allowable

[redacted] for leachable substances." The margin of safety for all six compounds was [redacted] Therefore, based on the results of these chemical characterizations, the toxicological risk assessment concluded that the use of the CleanCision™ System would not be expected to result in exposure to chemicals during clinical use at levels that would result in an adverse biological response in patients.

C. Conclusions

In summary, the CleanCision™ System was evaluated to determine the potential for toxicity resulting from contact of the device component materials with the body. The results of this testing demonstrate that the CleanCision™ System is biocompatible when used as intended.

SHELF LIFE/STERILITY

The CleanCision™ System is packaged in a Tyvek / Polyethylene-Nylon pouch and is sterilized using [redacted]. The validation of the sterilization process complies with [redacted] -- Requirements for the development, validation and routine control of a sterilization process for medical devices." The sterilization method achieves a sterility assurance level (SAL) of 10^{-6}.

[redacted]

The identified shelf life of two (2) years was validated using [redacted] inspection of the packaging components and product labels, gross leak detection (bubble) testing for assessing package integrity, and seal strength (peel) testing for evaluating the pouch seal strength. In addition, microbial ranking testing for the pouch was conducted in accordance with ASTM F1608-00 "Standard Test Method for Microbial Ranking of Porous Packaging Materials."

PERFORMANCE TESTING – BENCH

Performance testing included actuation force testing, resistance to synthetic blood, tear and tensile strength, elongation characterization, flammability, fluid delivery and removal flow rate testing, and suction pressure testing. Testing was conducted on devices which had been exposed to (b)(4) sterilization, environmental conditioning, simulated distribution and simulated use, where applicable. Test results confirmed the CleanCision™ System met all device requirements. The device requirements are appropriate for the device's indications for use. Device performance was also verified after two years of accelerated aging by performing the following tests (Table 3) at zero and 24 months of accelerated aging. The tested samples met all requirements supporting a labeled shelf life of 2 years.

Table 3. – Summary of Non-clinical Performance Testing

Test	Purpose	Method	Acceptance Criteria	Results
Retraction Ring Actuation Force	Determine that the forces required to deploy the device clinically do not lead to device failures.	15 retraction assemblies placed in a simulated wound model; measured force required to actuate retraction ring	<10N	Pass
Resistance to Synthetic Blood	Evaluate barrier integrity by demonstrating the barrier material is resistant to penetration by blood.	ASTM F1670-08	Barrier material must be demonstrated to be resistant to synthetic blood.	Pass
Tear and Tensile Strength, Elongation Characterization	Determine the barrier material provides tear resistance, tensile strength and elongation properties.	ASTM D1004-13 ASTM D882-12	• Tear resistance must be equivalent to or greater than 500 PLI • Tensile Strength of 1500 PSI or greater • Elongation at break of 300% or greater	Pass
Flammability	Determine the device is not flammable and does not cause damage to the wound, tissue or organs during surgery.	NFPA[1] 702-1980	The burn length of the material must be less than the total length after a burn time of 10 seconds.	Pass
Irrigating Fluid Delivery Flow Rate	Determine that fluid delivery flow rates are able to remove debris from surgical wound to prevent tissue damage and infection.	15 devices connected to standard IV bag on IV pole and suspended over graduated cylinder. Roller clamp opened completely to allow fluid flow for 5 minutes. Measured flow rate.	Fluid delivery system must be able to deliver fluid at an average flow rate between 5mL/Min and 16 mL/min.	Pass

Test	Purpose	Method	Acceptance Criteria	Results
Suction Flow Rate	Determine that suction flow rates and pressures are not applied to patient tissue which could result in the inadvertent removal of or damage to tissue or organs during surgery.	15 devices submerged appropriately in 3-6" of tap water. Similar testing done using viscous fluids to represent worse case fluid conditions. The device was connected to suction. Measured suction rate.	Suction flow rate must be at least 10mL/min.	Pass
Tubing Connection Strength	Ensure fluid flow and removal is maintained during use.	Mount the test specimen onto tensile tester and balance the load. Pull to failure and record peak force.	>21.1N 21.1 N is the force required to remove the bag spike from a fluid bag and the tubing connection should be stronger so the bag spike would disconnect from the bag before the tubing would pull out of the pliable membrane.	Pass

[1] NFPA = National Fire Protection Association

PERFORMANCE TESTING – ANIMAL

An animal study was conducted to demonstrate proper device functioning under simulated use. The purpose was to evaluate the performance and safety of the CleanCision™ System in a simulated animal study under defined worst case conditions. A 6 hour abdominal surgical procedure simulated use of the device, and evaluated the local, regional, and systemic effects of the device in a porcine large animal model. Baseline and terminal CBC and Serum Chemistry Panel samples were collected and analyzed; terminal peritoneal fluid samples were collected and analyzed; and a complete necropsy was performed, including a gross assessment and procurement of appropriate tissue specimens for histological evaluation.

From the results provided, all animals had normal clinical observations at study enrollment and a normal baseline physical examination. All clinical pathology excursions were mild and clinically insignificant, none of which were believed to be test or control article related. In addition, all test devices were successfully placed and utilized as laid out in the study protocol and each device was successfully evaluated for all the device functions and parameters listed in the study protocol. All devices showed fluid flow patency throughout the procedure and operated as intended. Fluid that was run through the device was successfully removed through the suction port throughout the procedure. There were no procedural complications related to the use of the test device during the procedure. The study surgeon was successfully able to insert, remove and reinsert the device without any complication for the duration of the procedure. There was no evidence of inflammation,

infection or inadvertent organ aspiration from the cytology analysis. No important adverse device-related gross or microscopic lesions were identified in the surgical wound margins, abdominal tissues in contact with the device, or in more distant systemic organs. There was no evidence of hematoma at the surgical site, tissue trapping under the device, denudation of the peritoneum or any organ serosa, tissue erosion or maceration, adhesions, or evidence of bacterial infection. At least 14 tissues with serosa in contact with the device were examined and particulates were not identified using bright field and polarized light.

The results of this study, in combination with the bench testing described above and the usability testing described below, established the usability of this device and demonstrated that the benefits of this device outweigh the risks.

HUMAN FACTORS/ USABILITY

The Human Factors / Usability Validation Testing was performed to confirm the risk assessments and to identify any unforeseen use-related hazardous situations with this device. The usability validation testing consisted of a cadaver study to determine whether the CleanCision™ System is successfully able to meet surgeon-user needs with respect to its usability and functionality throughout the entirety of its intended use, and by extension determining whether the technical usability of the device is acceptable for clinical use in patients.

CleanCision™ System performed at an equivalent level compared to current devices on the market for barrier wound protection and retraction. Surgeons found that the force required to deploy the device was acceptable, which was less than 10N. In addition, the effectiveness of the fluid delivery and retrieval mechanism was rated uniformly high by the surgeon-user. The feedback specifically indicated that the device should prevent the majority of fluid from leaking into the abdominal cavity. All users were able to successfully insert, utilize, and remove the device as expected. No unacceptable risks were identified during the usability testing.

The results of this study, in combination with the bench testing and animal study described above, established the usability of this device and demonstrated that the benefits of this device outweigh the risks.

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

Labeling for the CleanCision™ System includes Instructions for Use, which includes the intended use, product description, contraindications, warnings and precautions (contraindications and warnings are identified above, under Limitations).

The labeling provided is adequate and includes appropriate information regarding specifications, instructions for the surgeon on proper use and removal, as well as an appropriate prescription statement as required by 21 CFR 801.109.

RISKS TO HEALTH

Table 4 below identifies the risks to health that may be associated with use of Irrigating Wound Retractor Device and the measures necessary to mitigate these risks.

Table 4. – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Adverse Tissue Reaction	Biocompatibility Evaluation
Tissue or Wound Damage	Non-clinical Performance Testing Shelf Life Testing Labeling
Infection	Sterilization Validation Non-clinical Performance Testing Shelf Life Testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the Irrigating Wound Retractor Device is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible and evaluated for particulate matter.
2. Performance data must demonstrate the sterility and pyrogenicity of the patient-contacting components of the device.
3. Performance data must support shelf life by demonstrating continued functionality and sterility of the device over the identified shelf life.
4. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must:
    a. Characterize the tear resistance, tensile strength, and elongation properties of the barrier material;
    b. Demonstrate that the liquid barrier material is resistant to penetration by blood, and is non-flammable;
    c. Characterize the forces required to deploy the device;
    d. Characterize the device's ranges of operation, including flow rates and maximum suction pressures;
    e. Demonstrate the ability of the device irrigation apparatus to maintain a user defined or pre-set flow rate to the surgical wound;
    f. Demonstrate the ability of the device to maintain user defined or pre-set removal rates of fluid from the surgical wound.

5. The labeling must include or state the following information:
    a. Device size or incision length range;
    b. Method of sterilization;
    c. Flammability classification;
    d. Non-pyrogenic;
    e. Shelf life;
    f. Maximum flow rate and suction pressure.

BENEFIT/RISK DETERMINATION

The risks of the device are based on biocompatibility studies and non-clinical performance testing. The risks include adverse tissue reaction, tissue or wound damage and infection. There are alternative devices in the market for wound retraction and wound protection. However, the current device is unique in design because it includes a system for delivery and removal of fluid to and from the wound edge.

The probable benefits of the device are also based on non-clinical laboratory, animal studies, and usability testing. The probable benefits for the CleanCision™ Wound Retraction and Protection System include wound retraction and barrier protection to the edge of the surgical incision.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the data support that for use of the device by a surgeon during abdominal surgery to retract the surgical incision, provide access to the abdominal cavity, and irrigate the surgical wound edge, the probable benefits outweigh the identified risks to health for the CleanCision™ Wound Retraction and Protection 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 CleanCision™ Wound Retraction and Protection System is granted and the device is classified under the following:

Product Code: PQI
Device Type: Irrigating Wound Retractor Device
Class: II
Regulation: 21 CFR 878.4371