October 25, 2017

Prescient Surgical, Inc.
Lisa Claude
Sr. Director of Clinical and Regulatory Affairs
1585 Industrial Rd.
San Carlos, California 94070

Re: K172132
Trade/Device Name: CleanCision Wound Retraction and Protection System
Regulation Number: 21 CFR 878.4371
Regulation Name: Irrigating Wound Retractor Device
Regulatory Class: Class II
Product Code: PQI
Dated: September 20, 2017
Received: September 22, 2017

Dear Lisa Claude:

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 (DICE) 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 (DICE) 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,

Michael J. Ryan -S

for Tina Kiang, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172132

Device Name
CleanCision™ Wound Retraction and Protection System

Indications for Use *(Describe)*
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.

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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510(K) SUMMARY – K172132

GENERAL INFORMATION

Submitted By:	Prescient Surgical 1585 Industrial Road San Carlos, CA 94070 Tel: 650-489-5025
Contact Person:	Lisa Claude lclaude@prescientsurgical.com
Date Prepared:	October 25, 2017
Device Trade Name:	CleanCision™ Wound Retraction and Protection System
Common Name:	Irrigating Wound Retractor Device
Classification:	Class II
Regulation Number:	21 CFR 878.4371
Regulation Title:	Irrigating Wound Retractor Device
Product Code:	PQI
Classification Panel:	General and Plastic Surgery
Predicate Device:	DEN150038 - CleanCision™ Wound Retraction and Protection System

DEVICE DESCRIPTION

The CleanCision™ Wound Retraction and Protection System is a sterile, single-use irrigating wound retractor device that integrates surgical retraction, wound barrier protection, and fluid delivery and removal. The wound barrier protection component is comprised of a flexible, double-walled sheath with an impermeable inner layer that protects the wound edges from 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. Fluid is delivered via gravitational feed from an external fluid bag into the device and delivered to the wound edges through the permeable outer layer of the sheath. Excess fluid is removed through the bottom ring via a connection with the hospital's standard vacuum suction mechanism.

INTENDED 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.

The subject device has identical intended use and indications for use as the predicate device.

SUMMARY COMPARING THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same principle of operation as the predicate device. An additional device size was developed to accommodate smaller incision lengths. There were also some minor design modifications made to the subject device. This submission includes the following changes in technological characteristics.

- Dimensional changes to accommodate new incision range (new device size)
- Updated upper retraction ring to improve user experience
- Adjusted the fluid delivery pathway
- Adjusted the fluid removal pathway
- Updated materials
- Updated packaging configuration

Comparison of CleanCision System to Predicate Device		
	Predicate Device (DEN150038)	**This Submission (K172132)**
Manufacturer	Prescient Surgical	Same
Device Trade Name	CleanCision Wound Retraction and Protection System	Same
Incision Range	**7-16 cm**	**3-9 cm**
Common or Usual Name	Irrigating Wound Retractor Device	Same
Classification	Class II	Same
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.	Same
Technological Characteristics		

Comparison of CleanCision System to Predicate Device		
	Predicate Device (DEN150038)	**This Submission (K172132)**
Principle of Operation	A wound retractor device that integrates surgical retraction, wound barrier protection, and fluid delivery and removal.	Same
Design Features		
Device Dimensions	Upper Ring Diameter (fully expanded): **23**cm Sheath Length: **13**cm Bottom Ring Diameter: **16**cm	Upper Ring Diameter (fully expanded): **21**cm Sheath Length: **10**cm Bottom Ring Diameter: **9**cm
Retraction	Sheath connected to bottom ring and expanding top ring	Same
Barrier Protection	Flexible, double-walled sheath with an impermeable inner layer	Same
Fluid Irrigation	Fluid delivered via gravitational field from an external sterile irrigation solution bag into the devices and delivered to the wound edges through the permeable outer layer of the sheath	Fluid delivered via gravitational field from an external sterile irrigation solution bag into the devices and delivered to the wound edges through the permeable outer layer of the sheath **via a modified fluid delivery pathway**.
Fluid Removal	Excess fluid removed through a separate chamber **within the sheath** via a connection with the hospital's standard vacuum suction mechanism.	Excess fluid is removed through a separate chamber **within the bottom ring** via a connection with the hospital's standard vacuum suction mechanism.
Key Component Materials		
Semi-Rigid Polymer Top Ring	Polycarbonate	Polycarbonate **and ABS**
Semi-Rigid Polymer Bottom Ring	Urethane	Same
Flexible Polymer Sheath	Polyurethane	Same
Sterilization		
Single Use	Yes	Same
Provided Sterile	Yes	Same
Sterilization Method	Ethylene Oxide	Same
Sterilization Assurance Level	10^{-6}	Same
EO Residuals	Meets requirements of 1SO 10993-7	Same
Biocompatibility	Meets requirements of ISO 10993-1 and *Use of International Standard ISO 10993-*	Meets requirements of ISO 10993-1 and *Use of International Standard ISO 10993-*

Comparison of CleanCision System to Predicate Device		
	Predicate Device (DEN150038)	**This Submission (K172132)**
	1, Guidance for Industry and Food and Drug Administration Staff including: • Chemical Characterization (ISO 10993-18) • Cytotoxicity (ISO 10993-5) • Irritation (ISO 10993-10) • Sensitization (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Material-Mediated Pyrogenicity (ISO 10993-11) • Limulus Abebocyte Lysate (LAL) Bacterial Endotoxin Test (USP 85) • Hemocompatibility – Hemolysis (ISO 10993-4 and ASTM F756) • Particulate Testing (USP 788)	*1, Guidance for Industry and Food and Drug Administration Staff including:* • Chemical Characterization (ISO 10993-18) • Cytotoxicity (ISO 10993-5) • Irritation (ISO 10993-10) • Sensitization (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Material-Mediated Pyrogenicity (ISO 10993-11) • Limulus Abebocyte Lysate (LAL) Bacterial Endotoxin Test (USP 85) • Hemocompatibility – Hemolysis, Indirect Method (ISO 10993-4 and ASTM F756) • Particulate Testing (USP 788)
Packaging	Tyvek/ Polyethylene-Nylon Pouch	**Tyvek / PET-G Tray**
Other Technological Features		
Sheath Material Properties (Tensile Strength, Elongation, Tear Strength)	Tested in accordance with ASTM D1004 and ASTM D882	Same
Barrier Material Resistant to Penetration by Blood	Tested in accordance with ASTM 1670	Same
Flammability	Normal Flammability	Same
Surgical Drape Properties	Meets requirements of Barrier Performance Class Level 4	Same
Energy Source	No energy source used	Same

NON-CLINICAL PERFORMANCE DATA

Performance testing was repeated to ensure that the new design met the same essential performance specifications and conforms to all the requirements listed in the special controls for *Irrigating Wound Retractor Devices* (21 CFR 878.4371). The following performance testing

confirmed the CleanCision Wound Retraction and Protection System in this submission to be substantially equivalent to the predicate device.

- The device was tested in accordance with ISO 10993-1:2009 and *"Use of International Standard ISO 10993-1, Biological Evaluation of medical devices – Part 1: Evaluation of testing within a risk management process – Guidance for Industry and Food and Drug Administration Staff"* and meets the requirements for externally communicating, tissue contacting, limited exposure devices including:
    - Chemical Characterization (ISO 10993-18)
    - Cytotoxicity (ISO 10993-5)
    - Irritation (ISO 10993-10)
    - Sensitization (ISO 10993-10)
    - Acute Systemic Toxicity (ISO 10993-11)
    - Material-Mediated Pyrogenicity (ISO 10993-11)
    - Hemocompatibility – Hemolysis, Indirect Method (ISO 10993-4 and ASTM F756)
- The device has been evaluated for particulate matter per <USP 788>:2012 and meets the requirements.
- The CleanCision System is sterilized using Ethylene Oxide and provides a sterility assurance level of 10^{-6}.
- The device has been evaluated per USP <85> and determined to be non-pyrogenic per the requirements of USP <161>.
- The materials used in the manufacture of the CleanCision System have been tested in accordance with ASTM D1004-13 and ASTM D882-12 and meet tensile strength, elongation, and tear resistance requirements.
- Liquid barrier material is resistant to penetration by blood per ASTM F1670-08.
- The device meets the requirements for normal flammability per NFPA 702-1980.
- Physical, functional and performance design verification was conducted and the CleanCision System passed the required testing including: forces required to deploy the device, fluid delivery, and fluid removal rates.
- Functional testing was repeated post aging to demonstrate continued functionality and sterility of the device over the identified shelf life.

CONCLUSION

The CleanCision Wound Retraction and Protection System has the same principle of operation and intended use as the predicate device (DEN150038). Performance testing demonstrated that the subject device performs as intended and conforms to all the requirements listed in the special controls. In conclusion, the CleanCision Wound Retraction and Protection System is substantially equivalent in design, clinical use, principle of operation, materials and physical / functional characteristics to the legally marketed predicate device.