



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2016

Prescient Surgical
Mr. Jonathan Coe
President and CEO
1585 Industrial Road
San Carlos, CA 94040

Re: DEN150038
CleanCision™ Wound Retraction and Protection System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 878.4371
Regulation Name: Irrigating Wound Retractor Device
Regulatory Classification: Class II
Product Code: PQI
Dated: August 11, 2015
Received: August 13, 2015

Dear Ms. Claude:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the CleanCision™ Wound Retraction and Protection System, a prescription device under 21 CFR Part 801.109 that is *indicated 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.*

FDA concludes that this device should be classified into class II. This order, therefore, classifies the CleanCision™ Wound Retraction and Protection System, and substantially equivalent devices of this generic type, into class II under the generic name, Irrigating Wound Retractor Device.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1)

of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On August 13, 2015, FDA received your *de novo* requesting classification of the CleanCision™ Wound Retraction and Protection System into class I or II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CleanCision™ Wound Retraction and Protection System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the CleanCision™ Wound Retraction and Protection System *indicated 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,* can be classified in class II with the establishment of special controls for class II. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – 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

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.

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type submit a premarket notification containing information on the Irrigating Wound Retractor Device they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Terrell Cunningham at (301)-796-6299

Sincerely,

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health