



Food and Drug Administration  
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December 20, 2016

Alesi Surgical  
c/o Michele Lucey, Regulatory Consultant  
Lakeshore Medical Device Consulting, LLC  
128 Blye Hill Landing  
Newbury, NH 03255

Re: DEN150022  
Ultravision™ Visual Field Clearing System  
Evaluation of Automatic Class III Designation – *De Novo* Request  
Regulation Number: 21 CFR 878.5050  
Regulation Name: Surgical smoke precipitator  
Regulatory Classification: Class II  
Product Code: PQM  
Dated: May 20, 2015  
Received: May 26, 2015

Dear Ms. Lucey:

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 Ultravision™ Visual Field Clearing System, a prescription device under 21 CFR Part 801.109 that is indicated *for the clearance of smoke and other particulate matter that is created during laparoscopic surgery*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Ultravision™ Visual Field Clearing System, and substantially equivalent devices of this generic type, into class II under the generic name, Surgical smoke precipitator.

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.

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 May 26, 2015, FDA received your *de novo* requesting classification of the Ultravision™ Visual Field Clearing 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 Ultravision™ Visual Field Clearing 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 Ultravision™ Visual Field Clearing System, indicated *for the clearance of smoke and other particulate matter that is created during laparoscopic surgery*, 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

<b>Identified Risk</b>	<b>Mitigation Measures</b>
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	Animal testing Software verification, validation, and hazard analysis Labeling

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.

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 must submit a premarket notification containing information on the Surgical smoke precipitator 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 Mr. Steven Elliott at (301) 796-5285.

Sincerely,

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