DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 30, 2017

I.C Medical, Inc.
Elena S. Buiga
Director Of RA/QA/ISO
2340 W. Shangri La Rd.
Phoenix, Arizona 85029

Re: K163659
Trade/Device Name: Crystal Vision
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-Handling Apparatus For A Surgical Operating Room
Regulatory Class: Class II
Product Code: FYD
Dated: September 26, 2017
Received: October 3, 2017

Dear Elena S. Buiga:

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 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 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, Ph.D.
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)*

Device Name
Crystal Vision Smoke Evacuator System with Accessories

Indications for Use *(Describe)*
The Crystal Vision Smoke Evacuator System with Accessories is intended to remove smoke created in surgical procedures.

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

Submitter/Holder:

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Contact Person: Elena Simona Buiga
Director of RA/QA/ISO
simonab@icmedical.com

Date Prepared: October 23, 2017

Device:

Device Name:	Crystal Vision Smoke Evacuator System with Accessories
Trade Name:	Crystal Vision
Common Name:	Smoke Evacuator System with Accessories
Classification Regulation:	21CFR878.5070
Classification Name:	Apparatus, Exhaust, Surgical
Regulation Description:	Air-handling apparatus for surgical operating room.
Device class:	2
Product code:	FYD

Predicate Device:

Crystal Vision (Model 470) and Accessories K932230

Device Description:

The Crystal Vision Smoke Evacuator System with Accessories is designed to remove smoke created in surgical procedures. The Crystal Vision Smoke Evacuator System with Accessories can be used to remove smoke produced by lasers, electrosurgical devices, argon beam coagulators, LEEP devices, and other devices that create smoke during surgical procedures.
During internal surgical procedures such as laparoscopy, it helps to maintain the desired internal pressure (pneumoperitoneum). The Crystal Vision Smoke Evacuator System with Accessories removes up to 20 liters-per-minute of smoke produced.
The Crystal Vision Smoke Evacuator System with Accessories automatically activates when active (smoke producing) devices that are coupled to the smoke evacuator, with special sensors, are turned on.
The Crystal Vision Smoke Evacuator System with Accessories automatically turns off, at a time predetermined by the operator, after the active device turns off and automatically activates when the high pressure limit is exceeded in the pneumoperitoneum and it remains running to remove smoke, vapors, and gases until the internal pressure returns to levels below the preset maximum.
The Crystal Vision Smoke Evacuator System with Accessories can be used to evacuate CO_2 gas from the pneumoperitoneum at the end of laparoscopic procedures.
The Crystal Vision Smoke Evacuator System with Accessories is intended to be used by trained professionals.

The subject device (Crystal Vision Smoke Evacuator System with Accessories) operates under same technologies, same mechanism of actions as the predicate (Crystal Vision (Model 470) and Accessories) and will use same accessories as the predicate device.

The modifications are: increase dimension of the product chassis to partially enclose the Input ULPA filter and the Output Charcoal filter; replace mechanical controls with push buttons; eliminate Stand By switch; replace flow set display, from bargraph display to 3 digits display; expand flow reading from 2 to 3 digits.

Accessories description:

The ULPA Filter & Water Trap:
The ULPA Filter & Water Trap for the Crystal Vision Smoke Evacuator System with Accessories, like the filters for the predicate device, is a replaceable filter that is completely enclosed to protect health care personnel from potential contamination during filter change. The ULPA Filter & Water Trap has a ULPA (Ultra Low Penetration Air) media.

Charcoal Output Filter:
The Charcoal Output Filter for the Crystal Vision Smoke Evacuator System with Accessories, like the one for the predicate device, is a replaceable filter that is completely enclosed and installed on the back of the Crystal Vision Smoke Evacuator System. The filter contains Granular Activated Charcoal from coconut shell and its life is based on the ability of the charcoal to absorb odors.

Sensor:
The Sensor for the Crystal Vision Smoke Evacuator System with Accessories, like the sensor for the predicate device, is an accessory which activates the Crystal Vision Smoke Evacuator automatically, when a cutting, smoke producing device will activate.

Foot Pedal:
The foot pedal is used for end user convenience as to activate the smoke evacuator when needed. The foot pedal shall be connected through same input connector used by sensor(s).

Intra-Abdominal Tubing Set, Sterile and Non-Sterile:
The I/A tubing is used during laparoscopic procedures, to evacuate the smoke produced. It connects to the trocar at one end and to the smoke evacuator to the other end.

Smoke Tubing, Sterile and Non-Sterile:
The smoke tubing may be used during any surgical procedure where there are smoke producing devices that needs smoke evacuation.

Smoke Tubing with In-Line Filter, Non-Sterile:
The smoke tubing may be used during any surgical procedure where there is smoke producing devices that needs smoke evacuation. In addition, the smoke tubing has a HEPA filter

Wand, Sterile and Non-Sterile:
The wand is a hand held device that may be used during any surgical procedure where there is smoke producing devices that needs smoke evacuation.

Indication for Use:

The Crystal Vision Smoke Evacuator System with Accessories is intended to remove smoke created in surgical procedures

Comparison of Technological Characteristics with the Predicate Device:

This Special 510(k) is a modification to the dimension of the product chassis (partial enclosure of the Input ULPA filter and Output Charcoal filter); replacement of mechanical controls with push buttons; elimination of the Stand By switch; ; replace flow set display, from bargraph display to 3 digits display; expand flow reading from 2 to 3 digits for the previously FDA cleared 510(K) number K932230.

No changes were made to the intended use, indication for use, energy type, performance specifications, materials, sterilization method or fundamental scientific technology.

Performance Characteristics:

Performance Bench Testing:

The Crystal Vision Smoke Evacuator and its Accessories were exposed to performance bench testing to ensure conformance to:

ANSI/AAMI/ES 60601-1-Medical electrical equipment-Part 1: General requirements for basic safety and essential performance;

IEC 60601-1-2-Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances –Requirements and tests;

The Crystal Vision Smoke Evacuator and its Accessories met the acceptance criteria on all applicable clauses of above mention standards.

Clinical testing:

N/A

Conclusions:

The subject device-Crystal Vision Smoke Evacuator System with Accessories, is substantially equivalent to the predicate device- Crystal Vision (Model 470) and Accessories.