February 26, 2018

Cipher Surgical Ltd
David Bentley
Regulatory Consultant
The Venture Centre, Sir William Lyons Road
Coventry, West Midlands CV4 7EZ
UK

Re: K171637
Trade/Device Name: OpClear® System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX, FEQ
Dated: June 18, 2017
Received: June 23, 2017

Dear David Bentley:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171637

Device Name
OpClear® System

Indications for Use *(Describe)*
The OpClear® System consists of a reusable control unit and a range of disposable sterile single-use accessories intended to remove visual obstructions such as condensation, blood and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintaining a clear image of the surgical site.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Date Prepared: Feb 26, 2018

Submitters Information:

Submitters Name	Cipher Surgical Limited
Address	The Venture Centre Sir William Lyons Road Coventry CV4 7EZ UK
Contact Person	Justin Buch Operations Director Tel: +44 2477 170700 jbuch@ciphersurgical.com

Product Name:

Trade or Proprietary Name	OpClear® System
Common Name	Endoscope lens cleaning and defogging device
Classification Name	Laparoscope, General and Plastic Surgery
Classification	Class II
Classification Regulation:	21 CFR 876.1500 (Endoscope and accessories)
Product code:	FEQ, OCX

Predicate Devices:

The predicate device for the OpClear® System along with its 510(k) number is provided below:

Device Name	Manufacturer	510(k) Number
Clear-Vu System	Minimally Invasive Devices LLC	K080613

Device Description:

OpClear® System is a laparoscopic lens cleaning device which is intended to be used during any laparoscopic surgical procedure where there is a potential for contamination of the distal lens. Consisting of a reusable control unit and a range of sterile, invasive, single use disposables, it is intended to maintain surgical vision by removing contaminants such as condensation, blood, peritoneal fluid, smoke, fat and tissue smears that have contaminated the distal lens of the laparoscope during surgical procedures.

OpClear® System is composed of a control unit and a range of disposable accessories as shown below.

OpClear® Control Unit

Description	Part Number
OpClear Control Unit	CS-CU15-03

OpClear® Disposables

Description	Part Number
OpClear 314mm x 10mm x 30°	CS-SZ10-30
OpClear 314mm x 10mm x 0°	CS-SZ10-00
OpClear 328mm x 10mm x 30°	CS-SR10-30
OpClear 328mm x 10mm x 0°	CS-SR10-00
OpClear 300mm x 10mm x 0°	CS-OS10-00

OpClear® System is for professional use in a theatre environment, during all Laparoscopic procedures. It is suitable for use in all adult patients who have been selected by their physician / surgeon for laparoscopic surgery using 10mm laparoscopes of a compatible length / type.

Indications for use:

The OpClear® System consists of a reusable control unit and a range of disposable sterile single-use accessories intended to remove visual obstructions such as condensation, blood and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintaining a clear image of the surgical site.

Operating Principle:

During MIS, the laparoscope lens window is the surgeon's eyes and it can become covered in body fluids: peritoneal fluid, blood, and fat as well as tissue particulate or condensation impairing the surgeon's vision (via an external monitor/screen). Traditionally, cleaning the lens window of the laparoscope as a result of soiling required its removal of the laparoscope from the patient's abdomen which results in increased risk of infection, increased surgical duration, compromised surgeon workflow and compromised vision.

The OpClear® System uses carefully controlled timed flows of CO2 and saline delivered to the lens surface to maintain a clear vision and remove/reduce the need to remove the laparoscope during a surgical procedure.

<u>OpClear® Control Unit</u>
The OpClear® Control Unit is a mains powered medical device which is connected to the electrical mains supply and to either a CO_2 bottle or CO_2 wall supply.

It supplies, on demand, CO_2 to the distal lens of the laparoscope (via the OpClear® Disposable) and CO_2 to operate the plunger of the sterile disposable wash cartridge.

The surgeon makes the selection of either demist function or wash function by operating a pneumatic foot switch control as and when required. Full details of the operation of the device are given in the instructions for use.

OpClear® Disposable

The OpClear® Disposable is a sterile, invasive, single use accessory to the OpClear® control unit, which is fitted to a compatible laparoscope immediately prior to the start of the surgical procedure. The disposable directs the CO2 and saline directly to the distal lens of the laparoscope in response to the surgeon's requirements. The CO_2 supply from the control unit is used to propel the plunger of the refillable 0.9% saline cartridge (which forms part of the disposable) and deliver the saline at the desired time and position.

Materials:

OpClear® Control Unit

The OpClear® control unit consists of a painted aluminium enclosure containing a power supply, control circuitry and an anodised aluminium manifold which supplies CO_2.

OpClear® Disposable

The OpClear® disposable consists of a co-polyester moulding which is bonded to the extruded PVC CO_2 and saline supply tubes. The wash cartridge is formed of a polypropylene barrel with a polyethylene piston.

The co-polyester moulding is the only invasive part of the disposable.

OpClear® Control Unit Specifications:

Applicable Gas: CO2 medical grade gas

- Maximum delivery pressure to OpClear® Control Unit less than 100bar
- Max delivery pressure from OpClear® Control Unit 1.25bar +/- 0.1bar.

Weight and Dimensions OpClear® Control Unit

- Weight 4.8 kg.
- Height 70mm maximum, Width 330mm maximum, Depth 300mm maximum.

Footswitch

- Pneumatic switch with 3m tube

Alarm

- The OpClear® System alarms comply with IEC 60601-1-8.

Predicate Device and Reference Device Comparison Table:

	Device	Predicate Device	Reference Devices	
Device Name	**OpClear® System**	**Clear-Vu System**	**WOM Insufflator 50L FM134**	**264305-20 electronic endoflator**
Manufacturer Name	Cipher Surgical Ltd	Minimally Invasive Devices LLC	World of Medicines GmbH	Karl Storz
Device Classification Regulation	21 CFR 876.1500	21 CFR 876.1500	21 CFR 884.1730	21 CFR 884.1730
Common Name	Endoscope lens cleaning and defogging device	Endoscope lens cleaning and defogging device	Carbon Dioxide Insufflator for Laparoscopy and Vessel Harvesting	Laparoscopic Insufflator
Classification Name	Accessory, Endoscope	Accessory, Endoscope	Insufflator Laparoscopic	Insufflator, Laparoscopic
Product Code(s)	FEQ, OCX	GCJ, KOG	HIF, OSV	HIF
510(k)	-	K080613	K153513	K962863

	Device	Predicate Device	Reference Devices	
Device Name	**OpClear® System**	**Clear-Vu System**	**WOM Insufflator 50L FM134**	**264305-20 electronic endoflator**
Intended Use / Indications for Use	The OpClear® system consists of a reusable control unit and a range of disposable sterile single-use accessories intended to remove visual obstructions such as condensation, blood and other tissue particulates from the distal lens of a laparoscope during surgery and therefore maintaining a clear image of the surgical site.	The Clear-Vu System is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.	Intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard, Paediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure.	Designed to facilitate the use of laparoscopes by distending the abdomen with CO2 gas during laparoscopic surgical and diagnostic procedures.
Environment of Use	Hospital Operating Theatre	Hospital Operating Theatre	Hospital Operating Theatre	Hospital Operating Theatre
Max CO2 flow rate	2.5 l/min continuous 6.4 l/min pulse	Dependent upon concomitant insufflator	50 l/min	20 l/min
Max CO2 pressure	27 mmHg	Dependent upon concomitant insufflator	30 mmHg	30 mmHg

	Device	Predicate Device	Reference Devices	
Device Name	**OpClear® System**	**Clear-Vu System**	**WOM Insufflator 50L FM134**	**264305-20 electronic endoflator**
Cleaning Solution	Saline 0.9% NaCl	Saline 0.9% NaCl	N/A	N/A
Compatible Devices	Selected standard rigid 10mm laparoscopes with 0º and 30º angle tips	Standard rigid 10mm laparoscopes with 0º, 30º and 45º angle tips	N/A	N/A
Sterility	Single use disposables - Ethylene Oxide sterilisation validated in accordance with ISO 11135-2014	Radiation sterilisation - ANSI / AAMI / ISO 11137-1:2006	Ethylene Oxide sterilisation validated in accordance with ISO 11135-2007	Reusable tubing suitable for steam sterilisation at 134ºC
Electrical Safety	Independently tested to IEC 60601-1:2005	N/A	Independently tested to IEC 60601-1:2005	Complies with IEC 60601-1
Electromagnetic Compatibility	Independently tested to IEC 60601-1-2:2007	N/A	Independently tested to IEC 60601-1-2:2007	Complies with IEC 60601-1
Software Controlled	Developed , tested and verified to IEC 62304:2006	N/A	Developed , tested and verified to IEC 62304:2006	Software controlled

Summary of Non Clinical Testing:

The Device has been developed in the laboratory using a simulated human abdominal cavity environment which includes the ability to set pressure, atmospheric composition (CO_2 rather than air), temperature, humidity and operational lighting environment. The suitability of this test chamber (as a simulation of the operating environment for the device) has been validated. The performance of OpClear® System has been optimised using this bench model. Performance validation has been performed following improvement in the operating parameters for the Device.