August 19, 2022

Cipher Surgical Limited
Krupa Srivastava
Regulatory Consultant
The Venture Centre, Sir William Lyons Road
Coventry, West Midlands CV4 7EZ
UNITED KINGDOM

Re: K221824
Trade/Device Name: OpClear Platform (CU3 DI3), OpClear Control Unit with Footswitch (CS-CU33), OpClear Disposable Procedure Kits (CS-10-00-300, CS-10-30-300, CS-10-00-315, CS-10-30-315, CS-10-00-330, CS-10-30-330, CS-05-00-290, CS-05-30-290), CS-05-00-300, CS-05-30-300, CS-05-00-315, CS-05-30-315
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX, FEQ
Dated: June 21, 2022
Received: June 23, 2022

Dear Krupa Srivastava:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221824

Device Name
OpClear® Platform

Indications for Use *(Describe)*
The OpClear® Platform consists of a reusable control unit and a range of disposable sterile single-use accessories intended to remove visual obstructions on the distal window of laparoscopes, such as condensation, blood and other tissue particulates, therefore maintaining a clear image of the surgical site.
The OpClear ®Platform is indicated for use in abdominal laparoscopy.

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.

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510(k) Summary

Cipher Surgical OpClear® Platform

510(k) SUMMARY

Date Prepared: 21 June 2022

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® Platform
Common Name	Endoscope lens cleaning and defogging device
Classification Name	Laparoscope, General and Plastic Surgery
Classification Regulation:	21 CFR 876.1500 (Endoscope and accessories)
Product code:	FEQ, OCX

Predicate Device:

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

Device Name	Manufacturer	510(k) Number
OpClear®System	Cipher Surgical Ltd.	K171637

Device Description:

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

OpClear® Control Unit

Description	**Part Number**
OpClear Control Unit with footswitch	**CS-CU33**

OpClear® Disposables

OpClear Part #	Diameter	Angle	Working Length
CS-10-00-300	10 mm	0°	300 mm
CS-10-30-300	10 mm	30° / 45°	300 mm
CS-10-00-315	10 mm	0°	315 mm
CS-10-30-315	10 mm	30° / 45°	315 mm
CS-10-00-330	10 mm	0°	330 mm
CS-10-30-330	10 mm	30° / 45°	330 mm
CS-05-00-290	5 mm	0°	290mm
CS-05-30-290	5 mm	30° / 45°	290mm
CS-05-00-300	5 mm	0°	300mm
CS-05-30-300	5 mm	30° / 45°	300mm
CS-05-00-315	5 mm	0°	315mm
CS-05-30-315	5 mm	30° / 45°	315mm

The OpClear® Platform is for professional use in a theatre environment and is indicated for use in abdominal laparoscopy. It is suitable for use in all Patients aged 12 years old and above who have been selected by their physician / surgeon for laparoscopic surgery using 10mm and 5mm laparoscopes of a compatible length / type.

Indications for use:

The OpClear® Platform consists of a reusable control unit and a range of disposable sterile single-use accessories intended to remove visual obstructions on the distal window of laparoscopes, such as condensation, blood and other tissue particulates, therefore maintaining a clear image of the surgical site.

The OpClear® Platform is indicated for use in abdominal laparoscopy.

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® Platform uses carefully controlled timed flows of CO_2 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 CO_2 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.

The OpClear® Disposable is available in both 10 mm and 5mm diameter variants suitable for either a 0° or angled (30° or 45°) rigid laparoscope.

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 supply pressure to OpClear® Control Unit less than 74bar
- Max delivery pressure from OpClear® Control Unit 1.35bar.

Weight and Dimensions OpClear® Control Unit

- Weight 5.8 kg.
- Height 80mm, Width 330mm, Depth 304mm (excluding connectors).

Footswitch

- Pneumatic switch with 3m tube

Alarm

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

Comparison of the modified device to the cleared predicate device

	Device	Predicate Device	Reference Device
Device Name	**OpClear® Platform CU3 DI3**	**OpClear® System CU3 DI2**	**WOM 45L core insufflator F114**
Manufacturer Name	Cipher Surgical Ltd	Cipher Surgical Ltd	World of Medicines GmbH
Device Classification Regulation	21 CFR 876.1500	21 CFR 876.1500	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
Classification Name	Accessory, Endoscope	Accessory, Endoscope	Insufflator Laparoscopic
Product Code(s)	OCX, FEQ	OCX, FEQ	HIF, OSV
510(k)	-	K171637	K063367

	Device	Predicate Device	Reference Device
Device Name	**OpClear® Platform CU3 DI3**	**OpClear® System CU3 DI2**	**WOM 45L core insufflator F114**
Device Description	The OpClear device uses carefully controlled timed flows of CO2 and saline delivered to the lens surface of a compatible laparoscope, during minimally invasive surgery to maintain a clear vision and remove/reduce the need to remove the laparoscope during a surgical procedure. It consists of a mains powered, microprocessor controlled, reusable control unit and a range of disposable sterile accessories.	The OpClear device uses carefully controlled timed flows of CO2 and saline delivered to the lens surface of a compatible laparoscope, during minimally invasive surgery to maintain a clear vision and remove/reduce the need to remove the laparoscope during a surgical procedure. It consists of a mains powered, microprocessor controlled, reusable control unit and a range of disposable sterile accessories.	A microprocessor controlled CO2 insufflator that consists of the following major components and features: a casing, a world power supply, pressure reducers, a venting system, redundant pressure measurement, a fluid sensor, a gas heater, a software controlled graphical user interface (GUI) touch screen and various setting keys and display elements. The Insufflator 50L FM134 is not intended to enter the sterile field, and cannot be sterilized. The device is to be used with specially designed single-use tube sets that are delivered sterile. Specifically, the proposed device is to be used with a single-use tube set with heating wire and integrated filter or with a single-use tube set with integrated filter but without heating wire.

	Device	Predicate Device	Reference Device
Device Name	**OpClear® Platform CU3 DI3**	**OpClear® System CU3 DI2**	**WOM 45L core insufflator F114**
Intended Use / Indications for Use	The OpClear® Platform 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, therefore maintaining a clear image of the surgical site. The OpClear Platform is indicated for use in abdominal laparoscopy.	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.	Intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure.
Environment of Use	Hospital Operating Theatre	Hospital Operating Theatre	Hospital Operating Theatre
Patient Population	Patients over the age of 12, who have been selected by their physician / surgeon for laparoscopic surgery using 5mm and10mm laparoscopes of a compatible length / type.	Adult patients who have been selected by their physician / surgeon for laparoscopic surgery using 10mm laparoscopes of a compatible length / type.	Patients undergoing laparoscopic surgery

	Device	Predicate Device	Reference Device
Device Name	**OpClear® Platform CU3 DI3**	**OpClear® System CU3 DI2**	**WOM 45L core insufflator F114**
CO_2 supply	High Pressure Gas Bottle or Low Pressure Central Supply	High Pressure Gas Bottle or Low Pressure Central Supply	High Pressure Gas Bottle
Max CO2 flow rate	Adult and Pediatric mode: 2.5 l/min continuous 14l/min pulse	2.5 l/min continuous 6.4 l/min pulse* *(* subsequently this has been determined to have been incorrectly calculated. The max pulse flow rate of the predicate is 14 l/min)*	High Flow mode 40l/min Bariatric mode 45 l/m Low Flow (pediatric) mode 20 l/m
Max CO2 pressure	Adult mode 27 mmHg Pediatric mode 21mmHg (Display increments are in 3mmHg)	27 mmHg	High flow mode (15 years and above) 30 mmHg Bariatric mode 70 mmHg Low flow (pediatric) mode (14 years and lower) 20 mmHg
Cleaning Solution	Saline 0.9% NaCl	Saline 0.9% NaCl	N/A
Power Source	Mains electricity powered control unit	Mains electricity powered control unit	Mains electricity powered

	Device	Predicate Device	Reference Device
Device Name	**OpClear® Platform CU3 DI3**	**OpClear® System CU3 DI2**	**WOM 45L core insufflator F114**
Compatible Devices	Selected standard rigid 5mm and 10mm laparoscopes with 0º,30º/45º angle tips	Selected standard rigid 10mm laparoscopes with 0º and 30º angle tips	N/A
Number of uses	Control Unit – Re-usable Disposable – Single Use (3 years)	Control Unit – Re-usable Disposable – Single Use (3 years)	Re-usable Tube sets- Single Use (3 years)
Sterility	Single use disposables - Ethylene Oxide sterilisation validated in accordance with ISO 11135-2014	Single use disposables - Ethylene Oxide sterilisation validated in accordance with ISO 11135-2014	Ethylene Oxide sterilisation validated in accordance with ISO 11135-2007
Electrical Safety	Independently tested to IEC 60601-1:2005	Independently tested to IEC 60601-1-2005	Independently tested to IEC 60601-1-2005
Electromagnetic Compatibility	Independently tested to IEC 60601-1-2-2014	Independently tested to IEC 60601-1-2-2007	Independently tested to IEC 60601-1-2-2007
Software Controlled	Developed, tested and verified to IEC 62304-2015	Developed, tested and verified to IEC 62304-2006	Developed, tested and verified to IEC 62304-2006

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 the predicate device, OpClear® System and the subject device, OpClear® Platform, have been validated using the same bench model.

Conclusion:

The proposed device has the same principles of operation and technological characteristics as the predicate device.
There are no significant changes to the materials, dimensions (except for the diameter) or to the assembly process of the disposables. No new biocompatibility testing is deemed to be required as compared to the predicate device.
The OpClear Control Unit main configuration remains the same. There is no impact to the previously carried out electrical safety or the EMC testing.
The sterilisation method remains the same and so does the sterile barrier.

In conclusion, OpClear® Platform does not adversely affect safety or effectiveness.