July 31, 2020

SIDAM s.r.l.
Andrea Tromba
Regulatory Affairs Manager
Via Statale Sud, 169
Mirandola (MO), 41037
Italy

Re: K192499
Trade/Device Name: Cyber Blade
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: June 18, 2020
Received: June 22, 2020

Dear Andrea Tromba:

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,

Martha W. Betz, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192499

Device Name
Cyber Blade

Indications for Use *(Describe)*
Cyber BLADE is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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5. 510(K) SUMMARY

Applicant / Manufacturer Name and Address:	SIDAM s.r.l. Via Statale Sud, 169 41037 San Giacomo Roncole MIRANDOLA (MO) - Italy
510(k) Contact Person:	Andrea Tromba Regulatory Affairs Manager SIDAM s.r.l. Email: andrea@sidamit.it Phone: +39 0535.25523 Fax: +39 0535.25635
Date Prepared:	31/07/2020
Device Name:	Cyber Blade
Classification:	Class II
Classification Name:	Endoscopes and accessories
Common name:	Laparoscope, General and Plastic Surgery
Regulation Number:	21 CFR 876.1500
Product Code:	GCJ
Main Predicate device **Secondary predicate device**	Versacut + Tissue Morcellator (K133272), Lumenis Ltd Morce Scope Set 8970 (K041610), Richard Wolf Medical Instruments Corp**.**

Performance Standards:
There are no mandatory performance standards for this device.

Description of the device:

Cyber Blade provides efficient and rapid morcellation under endoscopic visualization. The cutting action is driven by the motor in the handpiece.
Cyber Blade comprises:

- a single use sterile blade fixed to a handpiece where controls are placed
- a re-usable internal motor provided with integrated battery pack
- an AC powered charger for the battery pack

Cyber blade is also supplied with aspiration tubing and canister for the collection of evacuated tissue.

Cyber Blade is comprehensive of the following parts:

REF	Description	notes
20041001	Cyber Blade Morcellator	sterile single use
20042001	Battery-powered motor	non sterile - reusable
20049001	Charging station	100-220V, 50/60Hz
ABM000091	Suction tube	sterile single use
077.0562	Canister (tissue collector)	

Key Specifications, mechanism of action, device function	
Principle of operation	morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.
Vacuum intensity regulation	Possible through the leverage on the morcellator
Speed regulation	Possible through the button on the morcellator
Morcellation velocity 1	About 17 grams per minute
Handpiece dimension (external tube)	38 cm length 0.47 cm external diameter
Materials in contact with the tissue	Stainless steel
Power supply	The morcellator is battery powered. The battery charger is AC power supplied.
Supplied Sterile	Yes (only the morcellator)
Re-usable	No. The morcellator is single use only. Its internal motor is reusable

Indications for Use

Cyber BLADE is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.

Comparison of Technological Characteristics:

The subject device and the identified predicate devices have comparable general intended use and technological characteristics.

Any differences compared to the predicate devices do not present any new types of safety or effectiveness concern.

A comparison of the technical characteristics between the subject and predicate devices follows:

[1] The morcellated tissue coincides with the removed tissue, as all is aspired with the vacuum system

Specification	Subject device	main predicate device	Secondary predicate device	Comparison to Predicate
Device Name (K #)	Cyber Blade	VERSACUT + TISSUE MORCELLATOR (K133272)	MORCE SCOPE SET 8970 (K041610)	
Submitter	SIDAM s.r.l.	LUMENIS LTD.	RICHARD WOLF MEDICAL INSTRUMENTS CORP.	
Principle of operation	morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.	Morcellation through the cutting effect of the cutting window, produced by the relative movement of the internal tube and the external tube.	Same
Vacuum intensity regulation	Possible through the leverage on the morcellator	Possible from the vacuum generator	Possible from the vacuum generator	equivalent
Speed regulation	Possible through the button on the morcellator	Possible from the vacuum generator	Possible from the vacuum generator	equivalent
Handpiece dimension (external tube)	38 cm length 0.47 cm external diameter	39.5 cm length 0.47 cm external diameter	35 or 38 cm length 0.475 cm external diameter	In the same range
Materials in contact with the tissue	Stainless steel	Stainless steel	Stainless steel	equivalent
Power supply	The morcellator is battery powered. The battery charger is AC power supplied.	AC power supplied	AC power supplied	A device battery powered raises less concerns compared to a device AC powered
Suction pump	Not part of the system, must use an external suction system.	Part of the system	Part of the system	External FDA cleared suction system to be used.
Supplied Sterile	Yes	No	Yes	A device provided sterile raises less concerns compared to a device intended to be sterilized before use.
Re-usable	No. The morcellator is single use only. Its internal motor is reusable, but it never comes in contact with the patient	Yes	Available either single use and reusable	A single use device raises less concerns than a re-usable one.

Comparison of indications: as detailed in the comparison table below, the indications of the subject device are a sub-set of the indications of its predicate devices.

Specification	Subject device	main predicate device	additional predicate device	Comparison to Predicate
Device Name (K #)	Cyber Blade	VERSACUT + TISSUE MORCELLATOR (K133272)	MORCE SCOPE SET 8970 (K041610)	
Submitter	SIDAM s.r.l.	LUMENIS LTD.	RICHARD WOLF MEDICAL INSTRUMENTS CORP.	
Intended use	Cyber BLADE is intended for use under endoscopic visualization for the morcellation and removal of dissected benign prostatic hyperplasia (BPH) tissue during endoscopic surgical procedures in urology.	The VersaCut + Tissue Morcellator is intended for use under direct or endoscopic visualization for the morcellation and removal of dissected tissue during pelviscopic, laparascopic, percutaneous and open surgical procedures whenever access to the surgical site is limited.	Morce Scope Set 8970, in conjunction with a morcellation probe, and with its sheaths and obturators, is used in the cutting (morcellation) and continuous removal of large tissue masses. In combination with the corresponding auxiliary instruments, it can be used as a nephroscope in the disintegration and removal/aspiration of kidney and bladder stones and the removal of tumors via percutaneous (kidney) or transurethral (bladder) passages, in conjunction with	Sub-set of the indications of the predicate devices. Endoscopy is a less invasive access to the body compared to laparoscopy or other invasive techniques.

Specification	Subject device	main predicate device	additional predicate device	Comparison to Predicate
Device Name (K #)	Cyber Blade	VERSACUT + TISSUE MORCELLATOR (K133272)	MORCE SCOPE SET 8970 (K041610)	
Submitter	SIDAM s.r.l.	LUMENIS LTD.	RICHARD WOLF MEDICAL INSTRUMENTS CORP.	
			intracorporeal 5-4ithotripters e.g. operated pneumatically, by ultrasound, electro-hydraulically or by laser, under endoscopic control. The POWER CONTROL 2303 in conjunction with POWER STICK M4 serves to drive WOLF morcellators for the continuous removal of ablated tissue in endoscopic operations. The SUCTION PUMP is used for aspirating irrigation fluid in conjunction with a resectoscope or a morcellator following laser TURP.	

Summary of Non-Clinical Performance Testing :
Cyber Blade devices comply with the following recognized consensus standards or guidelines:

STANDARD TITLE or guidelines	standard recognized by FDA?	FDA recognition number	exclusions from the standard
IEC 60601-1:2012, ed 3.1, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	Yes	19-4	No
IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests	Yes	19-8	no
EN 556-1:2001/AC:2006 Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: requirements for terminally sterilized medical devices	No	N/A	No
ISO 15223-1 Third Edition 2016-11-01 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	Yes	5-117	No
EN 1041:2008 Information supplied by the manufacturer of medical devices.	No	N/A	No
ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Yes	2-245	No
ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]	Yes	2-220	No

STANDARD TITLE or guidelines	standard recognized by FDA?	FDA recognition number	exclusions from the standard
ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009)]	Yes	14-408	No
ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Yes	2-174	No
ISO 11135 Second edition 2014-07-15 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]	Yes	14-529	No
ISO 11138-1 Third edition 2017-03 Sterilization of health care products - Biological indicators - Part 1: General requirements	Yes	14-502	No
ISO 11607-1 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]	Yes	14-454	No
ISO 11607-2 First edition 2006-04-15 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]	Yes	14-455	No
ISO 11737-1 Third edition 2018-01 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product	Yes	14-514	No
ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices	Yes	5-40	No
ISO 17664 Second edition 2017-10 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	Yes	14-515	No
ISO 17664 Second Edition 2017-10 Processing Of Health Care Products - Information To Be Provided By The Medical Device Manufacturer For The Processing Of Medical Devices	Yes	14-515	No
Software Verification and Validation Testing Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	-	-	-

The following additional testing were performed: morcellation efficiency, suction test, dimensional specification verification, tensile strength of blade, comparative testing with Richard Wolf morcellator, risk analysis on the performance test, battery testing.

Conclusion

As the indications for use are a sub-set of its predicate devices and the principle of operation and specifications are equivalent, Cyber Blade is substantially equivalent to its predicate devices.