September 29, 2023

REGER Medizintechnik, GmbH
% Kr. Kenneth K. Kleinhenz, MBA
Principal Official Correspondent
QSR Consulting
4141 Elm Road
Hudson, Michigan 49247

Re: K231622
Trade/Device Name: REGER Nebulizer Irrigation Cannula
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 6, 2023
Received: September 8, 2023

Dear Mr. Kleinhenz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.09.29 13:43:08 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K231622

Device Name
REGER Nebulizer Irrigation Cannula

Indications for Use *(Describe)*
The REGER Nebulizer Irrigation Cannula is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from 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.

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Date Prepared: 27 September 2023

I. SUBMITTER

Manufacturer Name: REGER Medizintechnik,
GmbH Gewerbestrasse 10
Villingendorf, Germany 78667

Mfg. Establishment Registration Number: First premarket notification. Company to register with FDA within 30 days of 510(k) clearance.

Official Contact: Mr. Kenneth K. Kleinhenz, MBA
Principal
QSR Consulting
4141 Elm Rd.
Hudson, MI 49247
Telephone (619) 244-9573
Kleinhenz64@gmail.com

II. DEVICE

Name of Device:	REGER Nebulizer Irrigation Cannula
Common or Usual Name:	Laparoscope, General and Plastic Surgery
Classification Name	Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: Product Code:	GCJ
510(K) Identification:	K231622

III. PREDICATE DEVICE

Therma Solutions HurriChem, K222575

IV. DEVICE DESCRIPTION

Design Characteristics

The REGER Medizintechnik Nebulizer Irrigation Cannula is a sterile, single use stainless steel cannula with a polymer handle that is intended to nebulize irrigation fluids into the body during laparoscopic procedures. The sterile irrigation fluid is delivered from an injection pump (not provided) through the polymer tubing and into the stainless-steel shaft. The shaft has internal mechanics that deliver the fluid as microscopic droplets in a fine mist. The REGER Medizintechnik Nebulizer Irrigation Cannula is designed with a precision orifice at the tip for the deployment of a precise nebulized spray of irrigation solution into the laparoscopic cavity.

The REGER Medizintechnik Nebulizer Irrigation Cannula is straight and measures between 243-245 mm from Tip to the end of the handle with a shaft diameter ranging from 3.0 - 8.0 mm. The orifice at the head of the cannula shaft ranges in diameter of 0.17mm to 0.2mm. The REGER Medizintechnik Nebulizer Irrigation Cannula also contains a 10’ flexible 3.15mm outer diameter polymer tube at the handle end for attachment to attached to irrigation fluid injection pump (not provided) via a luer fitting.

Material Composition

The REGER Nebulizer Irrigation Cannula device is fabricated with biocompatible stainless steel and biocompatible polymers.

V. INDICATIONS FOR USE

The REGER Nebulizer Irrigation Cannula device is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The REGER Nebulizer Irrigation Cannula Device shares indications for use and design principles with the following predicate device: Therma Solutions HurriChem; a Class II medical device that was cleared for marketing in the United States under K222575.

Design and Materials

The REGER Nebulizer Irrigation Cannula device is substantially equivalent to the Therma Solutions HurriChem predicate device (K222575) in the following respects:

Criteria	Subject Device	Predicate Device	Substantially Equivalent
	REGER Medizintechnik Nebulizer Irrigation Cannula	**Therma Solutions HurriChem (K222575)**	
Device Description	Stainless steel cannula with small nebulizing outlet hole at the front and a flexible polymer tube at the back end to connect to irrigation fluid source / reservoir via a luer connection. The shaft has internal mechanics that deliver the irrigation fluid as microscopic droplets in a fine mist into the body during laparoscopic procedures.	Stainless steel cannula with small nebulizing outlet hole at the front and a flexible polymer tube at the back end to connect to irrigation fluid source / reservoir via a luer connection. The shaft has internal mechanics that deliver the irrigation fluid as microscopic droplets in a fine mist into the body during laparoscopic procedures.	Yes
Indications for Use	The Reger Nebulizer Irrigation Cannula is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.	The ThermaSolutions HurriChem Device Kit is indicated for use in patients undergoing a laparoscopic procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to lavage blood and tissue debris from the surgical site.	Yes (Same)

Criteria	**Subject Device**	**Predicate Device**	**Substantially Equivalent**
	REGER Medizintechnik Nebulizer Irrigation Cannula	**Therma Solutions HurriChem (K222575)**	
Design and Materials			
Dimensions			
Shaft Length	201-203 mm	206 mm	Yes
Shaft and Handle Length	243-245 mm	n.a.	Yes
Handle (OD)	12 mm	n.a.	Yes
Cannula Head OD	3.0– 10.3 mm	9.6 mm	Yes
Cannula Nozzle (OD)	0.17-0.20 mm	0.19 mm	Yes
Cannula Shaft (OD)	3.0 - 8.0 mm	8.00 mm	Yes
Performance			
Pressure at Nozzle Tip	116 – 261 psi	203 - 217 psi	Yes
Flow Rate	0.5 – 1.5 mL/sec	0.5 – 1.0 mL/sec	Yes
Flexible High Pressure Tubing (OD)	3.15 mm	3.5 mm	Yes
Flexible High Pressure Tubing (ID)	1.65 mm	1.80 mm	Yes
Tubing Connector	Luer Fitting, Male	Luer Fitting, Male	Yes
Average Droplet Size	20 – 35 micron	21 – 22 micron	Yes
Materials			
Cannula Shaft	Stainless Steel	Stainless Steel	Yes
Flexible High Pressure Tubing	Polyurethane	Polyurethane	Yes
Features			
Disposable	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Luer Connection	Yes	Yes	Yes
Sterilization Methodology			
EO Gas	Yes	Yes	Yes
Regulation	21 CFR 876.1500	21 CFR 876.1500	Yes
Product Code	GCJ	GCJ	Yes

VII. PERFORMANCE DATA

Biocompatibility Testing
The patient contact polymers and stainless steel were evaluated against the international standard ISO 10993-1 (Biological Evaluation of Medical Devices) and the FDA Guidance Document entitled, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process."

The battery of testing included:

- Cytotoxicity
- Sensitization
- Irritation
- Acute System Toxicity
- Material Mediated Pyrogenicity

Functional Testing
The REGER Nebulizer Irrigation Cannula Device was tested for various functional tests and shown to be substantially equivalent to the Therma Solutions HurriChem predicate device (K222575):

- Irrigation Flow Rate
- Irrigation Spray Angle
- Irrigation Spray Droplet Size
- Irrigation Spray Form
- Irrigation Spray Force
- Irrigation and Lavage Testing (Box Testing with Ink)
- Irrigation and Lavage Testing (Box Testing with Tissue)

Clinical Studies
No clinical studies were performed to support safety or effectiveness of the subject device.

VIII. CONCLUSIONS

The nonclinical testing demonstrates that the subject device is as safe and effective and performs as well as the legally marketed predicate device.