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.

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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.