January 15, 2021

Richard Wolf Medical Instruments Corporation
Michael Loiterman
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K201897
Trade/Device Name: Sensor-Ureterorenoscope 9 FR WL 600 MM (short RIWO D-URS), Adapter for Controller 5525
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: December 17, 2020
Received: December 18, 2020

Dear Michael Loiterman:

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,

Mark J. Antonino, M.S.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201897

Device Name
SENSOR-URETERORENOSCOPE 9 FR WL 600 MM
ADAPTER FOR CONTROLLER 5525

Indications for Use *(Describe)*
SENSOR-URETERORENOSCOPE 9 FR WL 600 MM

Sensor-Ureterorenoscopes are used within the scope of therapeutic and diagnostic interventions. The products are active, sterile and for single-use. They are used for visualizing body cavities via natural passages and for the insertion of auxiliary instruments through the working channel as well as the supply of irrigation fluid.
The Sensor-Ureterorenoscope is used in Urology for examination, diagnostics and/or therapy of the upper urinary tract.

User

These products are exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately instructed persons.

ADAPTER FOR CONTROLLER 5525

The products are used for operating a sensor endoscope in conjunction with an ENDOCAM Logic 5525 Camera Controller, for the mechanical connection to the sensor endoscope as well as for controlling the signals generated.

User

This product is designed exclusively for use by specialized medical personnel and may only be applied by medically qualified and adequately trained persons.

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.

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5 510(k) Summary

I Submitter

Richard Wolf Medical Instruments Corporation
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Vernon Hills, IL 60061

Phone:(847) 913 1113
Fax: (847) 913 0924

Contact Person, Title: Michael Loiterman, US Head of Regulatory - QA/QC
Date Prepared: December 16, 2020

Legal Manufacturer

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

II Device

Device name	Common name	Commercial name	Model Number(s)	Classification name	Regulation Number and Name	Product Code	Device Class
SENSOR-URETERORENOSCOPE 9 FR WL 600 MM	Ureteroscope	RIWO D-URS	473572075	Ureteroscope and Accessories, Flexible/rigid	876.1500 Endoscope and accessories	FGB	II
			473572076				
ADAPTER FOR CONTROLLER 5525	---	---	5525410				

III Predicate Device

Name of Predicate Device: Flexible Sensor Ureterorenoscope COBRA VISION EF (COBRA) (73561076)

510(k) Number: K183188

Regulatory Class: II

Product Code: FGB / FGA / ODC

Manufacturer: Richard Wolf GmbH

The predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

05 510(k) Summary

5.1 Subject Device Description

5.1.1 Device Identification

Type number	Description	Package unit
473572075	SENSOR-URETERORENOSCOPE 9 FR WL 600 MM	1
473572076	SENSOR-URETERORENOSCOPE 9 FR WL 600 MM	3
5525410	ADAPTER FOR CONTROLLER 5525	1

5.1.2 Device characteristics

Software

The RIWO D-URS and ADAPTER FOR CONTROLLER 5525 do not contain software.

Materials with patient contact

The RIWO D-URS includes components with direct and indirect patient contact.

The ADAPTER FOR CONTROLLER 5525 has no components with direct or indirect patient contact.

Single use / reusable

The RIWO D-URS is a single use device.

The ADAPTER FOR CONTROLLER 5525 is reusable and does requires cleaning and reprocessing during its use-life, i.e. users are required to clean and disinfect the device before every application and before returning for repairs. Methods of cleaning and reprocessing are detailed in the Instruction for Use.

Delivered sterile / non-sterile

The RIWO D-URS is delivered sterile.

The ADAPTER FOR CONTROLLER 5525 is delivered non-sterile.

Sterilization Method

The RIWO D-URS is sterilized with ethylene oxide.

The ADAPTER FOR CONTROLLER 5525 is not intended to be sterilized.

5.1.3 Environment of Use

The RIWO D-URS and ADAPTER FOR CONTROLLER 5525 are intended to be used in professional health care facility environment.

5.1.4 Brief Written Description of the Device

The Sensor-Ureterorenoscope features a semi-rigid instrument sheath and a flexible and actively deflectable tip. It is equipped with two separate working channels for applications with laser fibers and/or flexible auxiliary instruments. The two working channels have different diameters, allowing the insertion of the laser fiber via working channel (2) and a stone-extraction basket or flexible auxiliary instruments via working channel (1)

Irrigation is effected via working channel (1) and is connected via the luer connector marked in blue on the housing.

A third channel integrated in the instrument sheath allows the return flow via distal holes on the instrument head. The drain is effected via the lower luer connector marked in gray.

The flexible deflectable tip can be controlled in both directions (upward and downward) +/-300° via the control wheel on the handle. Thanks to the high torsional stiffness of the semi-rigid instrument sheath the sheath movements are transmitted directly in radial and axial directions. The working channel (2) permits the insertion of laser fibers up to a diameter of 272 µm.

For visualization the Sensor-Ureterorenoscope is connected to an endoscopy camera controller.

The Sensor-Ureterorenoscope is sterile and for single-use.

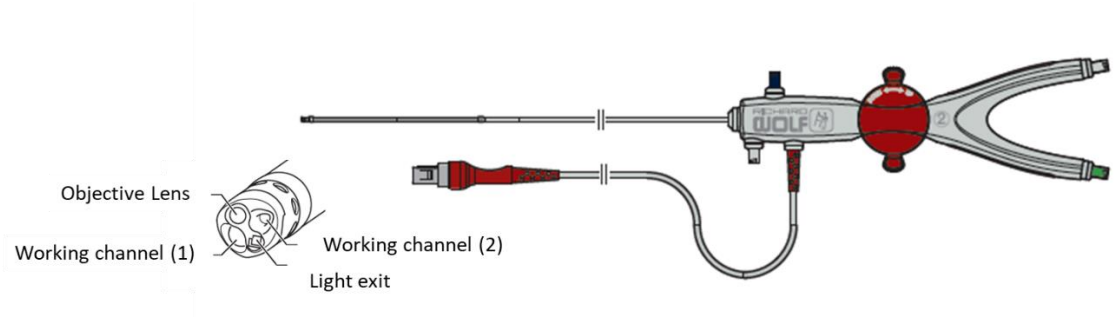

Figure 1: Image of the SENSOR-URETERORENOSCOPE 9 FR WL 600 MM with detailed display of the tip

The ADAPTER FOR CONTROLLER 5525 is an accessory to the RIWO D-URS, which serves as an interface to connect the RIWO D-URS to an ENDOCAM Logic 5525 Camera Controller (not part of this submission).

5.1.5 Materials of Use

The RIWO D-URS consists of stainless steel, glass, polymer, glue and instrument oil. The materials can come into direct and indirect body contact with the patient for a maximal contact duration of 3 hours.

The ADAPTER FOR CONTROLLER 5525 consists of stainless steel, polymer, composite, copper and gold. The materials do not have any body contact with the patient.

5.1.6 Key Performance Characteristics

The RIWO D-URS provides a deflection angle of 300° upwards and downwards, two working channels, a working length of 600 mm and a 160000 pixel CMOS sensor for imaging.

The ADAPTER FOR CONTROLLER 5525 provides electromechanical connectivity with a camera controller.

5.2 Indications for Use

5.2.1 Statement

SENSOR-URETERORENOSCOPE 9 FR WL 600 MM

Sensor-Ureterorenoscopes are used within the scope of therapeutic and diagnostic interventions. The products are active, sterile and for single-use. They are used for visualizing body cavities via natural passages and for the insertion of auxiliary instruments through the working channel as well as the supply of irrigation fluid.

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User

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5.2.2 Explanation on differences to predicate device

In comparison to the predicate device, the subject device does have only the urological indication of use and restricts usage of the device to natural passages.

However, the full indication of use for the subject device is covered by the predicate device and reducing the scope does not lead to new questions regarding safety and effectiveness.

5.3 Comparison of Technological Characteristics with the Predicate Device

5.3.1 Overview

Technolgical characteristic	Submitted device RIWO D-URS	Predicate device
Software	NA	NA
Materials with patient contact	Direct and indirect	Direct and indirect
Single use / reusable	Single use	Reusable
Delivered sterile / non-sterile	Delivered sterile	Non-sterile
Sterilization method	Ethylene oxide	Hydrogen peroxide

5.3.2 Discussion

There are some differences between the subject device and the predicate device that had to be verified or validated before claiming substantial equivalence.

Main difference:

I. The RIWO D-URS is a single use and sterile delivered device whereas the predicate device can be reprocessed which lead to changes in material, sterilization process, storage, etc.

Minor differences:

i. The RIWO D-URS requires the ADAPTER FOR CONTROLLER 5525 to establish the connection with an ENDOCAM Logic 5525 Camera Controller whereas the predicate device can be connected directly.

ii. The RIWO D-URS has a different handle design which requires different operation of the instrument.

iii. The RIWO D-URS is designed with small deviations in technical characteristics such as sheath diameter, working channel diameter, working length, deflection range, LED positioning and pixel size

I. For the main difference, several testing activities of the subject device were necessary to prove safety and effectiveness. This includes

- Storage and packaging validation of the sterile packaging
- Validation of the sterilization process
- Biocompatibility testing due to the new materials
- Performance testing due to new materials

i. The first minor difference was evaluated by bench testing and electromagnetic compatibility testing to prove the compatibility of the devices. Every functional performance test was done using the ADAPTER FOR CONTROLLER 5525 as otherwise no image would have been visible.

ii. The second difference was evaluated by a usability study which proved that the subject device can be operated as safe and effective as the predicate device.

iii. The third difference was evaluated by bench testing, proving that the deviations have no negative impact on the safety and effectiveness of the device and that it can perform within its specifications.

The following subsections provide an overview of the testing activities and methods, for more detail please check the applicable section.

5.4 Clinical Performance Testing

No clinical testing was performed with RIWO D-URS or ADAPTER FOR CONTROLLER 5525

No animal studies were performed with RIWO D-URS or ADAPTER FOR CONTROLLER 5525

5.5 Non-Clinical Performance Testing

5.5.1 Sterilization

The ethylene oxide sterilization process for the RIWO D-URS was validated according to EN ISO 11135:2014 Annex B (half-cycle method). The sterile packaging was subjected to several tests to ensure the sterility including

- Environmental conditioning ASTM D4169-16 and ASTM D4332-14
- Accelerated aging ASTM F1980-16
- Transportation Simulation ASTM D4169-16
- Visual Inspection of packaging and seal integrity ASTM F1886-16
- Packaging Challenging Testing [Bubble Test] ASTM F2096-11
- Seal Integrity Test [Liquid Dye] ASTM F1929-15
- Seal Strength Test ASTM F88-15

All test methods were applied to non-aged as well as accelerated aged products.

The ADAPTER FOR CONTROLLER 5525 is delivered non-sterile, therefore no validation was required.

The results proved that the RIWO D-URS is as safe as the predicate device and that the RIWO D-URS including ADAPTER FOR CONTROLLER 5525 can be deemed substantially equivalent to the predicate device.

5.5.2 Biocompatibility

The RIWO D-URS includes components with direct and indirect patient contact. Therefore, a biological risk assessment was performed considering the following:

- ISO 10993-1:2018: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- Use of International Standard ISO 10993,
  "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, issued June 16, 2016

The ADAPTER FOR CONTROLLER 5525 has no components with direct or indirect patient contact, therefore biocompatibility testing according to ISO 10993-1 was not necessary.

Biological testing and chemical characterization proved that the RIWO D-URS is as safe as the predicate device and that the RIWO D-URS including ADAPTER FOR CONTROLLER 5525 can be deemed substantially equivalent to the predicate device.

5.5.3 Electromagnetic Compatibility and Electrical Safety

Electromagnetic compatibility testing proved compliance with the following standards for RIWO D-URS including ADAPTER FOR CONTROLLER 5525

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 + A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

It could be shown that regarding electromagnetic compatibility and electrical safety the devices are as safe and effective and therefore substantially equivalent to the predicate device.

5.5.4 Performance and Operational testing

The efficacy and safety of Richard Wolf's RIWO D-URS including ADAPTER FOR CONTROLLER 5525 is documented by the verification and validation testing, which confirms that the product meets all the requirements and specifications for overall design, basic safety and essential performance, and that the design inputs and specifications are met.

This includes Packaging, Transportation, Environmental conditions, photobiological safety and functionality testing, performed for the RIWO D-URS as well as the ADAPTER FOR CONTROLLER 5525. In addition, a usability study was performed, and optical performance was evaluated for the RIWO D-URS and parameters without defined acceptance criteria were compared to those of the predicate device to prove equivalence.

It could be shown that the RIWO D-URS including the ADAPTER FOR CONTROLLER 5525 functions as safe as effective as the predicate device and therefore can be deemed substantially equivalent.

5.6 Conclusions

The non-clinical data support the safety of the device and the verification and validation demonstrate that the RIWO D-URS and ADAPTER FOR CONTROLLER 5525 should perform as intended in the specified use conditions. The data demonstrate that the RIWO D_URS and ADAPTER FOR CONTROLLER 5525 perform comparably to the predicate device that is currently marketed for an equivalent intended use.

Therefore, the RIWO D-URS with ADAPTER FOR CONTROLLER 5525 has been deemed to be substantially equivalent to the legally marketed device.