May 14, 2021

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

Re: K203226
Trade/Device Name: Telescope 0 O 10mm WL 305mm / Telescope 30 O 10mm WL 305mm / Telescope 50 O 10mm WL 305mm, Telescope 0 O 10mm WL 440mm / Telescope 30 O 10mm WL 440mm / Telescope 50 O 10mm WL 440mm
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ, HET, GCM
Dated: April 14, 2021
Received: April 15, 2021

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,

Long Chen, 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)*
K203226

Device Name
Rigid endoscopes TELESCOPE 0° Ø 10MM WL 305MM, TELESCOPE 30° Ø 10MM WL 305MM, TELESCOPE 50° Ø 10MM WL 305MM, TELESCOPE 0° Ø 10MM WL 440MM, TELESCOPE 30° Ø 10MM WL 440MM, TELESCOPE 50° Ø 10MM WL 440MM

Indications for Use *(Describe)*
The products are used in invasive surgery or via natural orifices for diagnosis and therapy and serve to visualize the inside of the body.
The products are used for interventions in different medical disciplines, such as surgery and laparoscopic interventions e.g. in urology and gynecology.

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

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Contact Person, Title: Michael Loiterman, US Head of Regulatory - QA/QC
Date Prepared: October 27, 2020

Legal Manufacturer
Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

II Device

The following Table 5-1 lists all devices for which clearance is requested:

Table 5-1: Devices for which clearance is requested including classification regulations, review panel, and device class.

Common name	Brand name	Trade name	Type Number	Product classification name	Product Code	Review Panel	Regulation Number and Name	Device Class
Telescopes	PANOVIEW Ultra telescopes	TELESCOPE 0° Ø 10MM WL 305MM	8934461	Laparoscope, General & Plastic Surgery & Endoscope, Rigid & Laparoscope, Gynecologic (And Accessories)	GCJ & GCM & HET	General & Plastic Surgery & Gastroen-terology / Urology & Obstetrics/ Gynecology	876.1500 Endoscope and accessories 884.1720 Gynecologic laparoscope and accessories	II
		TELESCOPE 30° Ø 10MM WL 305MM	8934462					
		TELESCOPE 50° Ø 10MM WL 305MM	8934463					
		TELESCOPE 0° Ø 10MM WL 440MM	89344416					
		TELESCOPE 30° Ø 10MM WL 440MM	89344426					
		TELESCOPE 50° Ø 10MM WL 440MM	89344436					

III Predicate Device

Name of Predicate Devices:

Type number	Trade name
8934.431	Endoscope 0° Ø 10MM
8934.432	Endoscope 30° Ø 10MM
8934.433	Endoscope 50° Ø 10MM

510(k) Number: K993103

Regulatory Class: II

Product Code: GCJ, GCM, (KOG)

Manufacturer: Richard Wolf GmbH

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

No reference devices were used in this submission.

5.1 Subject Device Description

5.1.1 Device Identification

Type number	Trade name
8934461	TELESCOPE 0° Ø 10MM WL 305MM
8934462	TELESCOPE 30° Ø 10MM WL 305MM
8934463	TELESCOPE 50° Ø 10MM WL 305MM
89344416	TELESCOPE 0° Ø 10MM WL 440MM
89344426	TELESCOPE 30° Ø 10MM WL 440MM
89344436	TELESCOPE 50° Ø 10MM WL 440MM

The PANOVIEW Ultra telescopes (common name: telescopes) are rigid endoscopes which are used in invasive surgery or via natural orifices for diagnosis and therapy and serve to visualize the inside of the body.

The products are used for interventions in different medical disciplines, such as surgery and laparoscopic interventions e.g. in urology and gynecology.

The submitted devices can be grouped by working length (WL) and direction of view.

5.1.2 Subject device characteristics

The following Table 5-2 describes the principal factors regarding the design and use of the telescopes.

Table 5-2: Subject device characteristics and their description.

Characteristics regarding	Description
Software	The submitted devices do not contain software.
Materials with patient contact	The submitted devices include components with direct patient contact and no patient contact.
Coatings	Coating of the lenses to increase the spectral range.
Single use / reusable	The submitted device are reusable devices. Users are required to clean, disinfect, and sterilize the device before every application and before returning devices for repair.
Delivered sterile / unsterile	The submitted devices are delivered unsterile.
Sterilization method	The submitted devices are sterilized via moist heat/steam sterilization.

DEVICE FUNCTIONALITY

The PANOVIEW Ultra telescopes (common name: telescopes) are rigid endoscopes with a fixed eyepiece, integrated light guide, optical system, cold light connector, with screw-on adapter for fiber light cables and with color coding ring for direction of view.

The telescopes are constructed of a cladding tube, which is surrounded by a rigid sheath, a fixed eyepiece and an eyecup at the proximal end (see Figure 5-1).

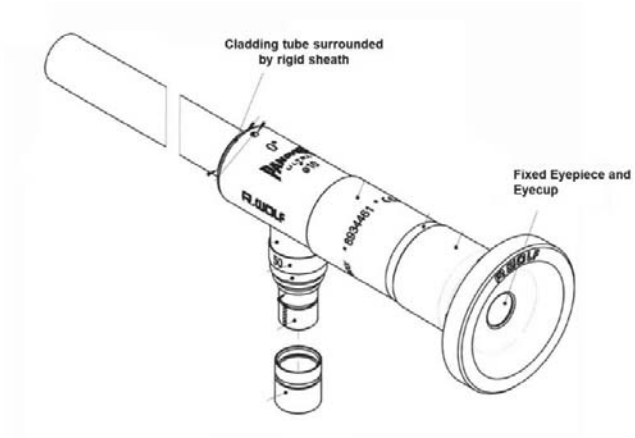

Figure 5-1: The telescopes are made of a cladding tube surrounded by a rigid sheath and a fixed eyepiece and eyecup.

Within the cladding tube, images are transferred via a rod lens system to the fixed eyepiece. Illumination is provided via light guide bundles connected to a light source. Visualization can directly be performed via the fixed eyepiece (direct visualization method) or alternatively via a monitor and user interface (indirect visualization method). For the second option, a camera must be attached to the fixed eyepiece and must be connected to a monitor.

5.1.3 Environment of Use

The telescopes are intended to be used in professional health care facility environment.

5.1.4 Materials of Use

The telescopes consist of optical glass and stainless steel which are in direct body contact. Moreover, the telescopes include glue and soft solder. The telescopes can be classified according to ISO 10993-1 as external communicating device with contact to tissue, bone and dentin for a limited duration (≤24h).

5.1.5 Key Performance Characteristics

The telescopes provide several directions of view (0°, 30°, 50°), a spectral range from 380 – 900 nm, two working lengths of 308 mm and 434 mm, and a working distance of 50 mm.

5.2 Indications for Use

5.2.1 Statement

The products are used in invasive surgery or via natural orifices for diagnosis and therapy and serve to visualize the inside of the body.

The products are used for interventions in different medical disciplines, such as surgery and laparoscopic interventions e.g. in urology and gynecology.

5.2.2 Explanation on differences to predicate device

In comparison to the predicate device, the subject device does not have the ENT indication.

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

The submitted devices basically share the technological characteristics of the predicate device. However, there are some improved characteristics and some differences due to technical progress when comparing the submitted devices with their predicate. Additionally, the submitted devices are available in two groups of working lengths, of which one is longer than that of the predicate device. The technical characteristics that differ between the predicate and the submitted devices are shaft thickness, the connection of the eyepiece, illumination fiber properties, whole system (image quality) properties, and the material of the window mount and the light guide bundle. To prove that those changed characteristics together with the increase in working length do not question safety and effectiveness of the submitted devices, several performance tests were performed, such as:

- Validation of the reprocessing process (*Section 14 – Sterilization and Shelf life*)
- Biocompatibility testing due to new materials (*Section 15 – Biocompatibility*)
- Performance testing due to the different working length, shaft thickness, new material of the light guide bundle, focal length, and distortion characteristics (*Section 18 – Performance testing bench*)
- Packaging validation of the subset with the working length 434 mm (*Section 18 – Performance testing bench*)

The main difference between the submitted devices and the predicate is the increased spectral range of the telescopes due to a VIS-NIR coating on the lenses. This increase in spectral range from 650 to 900 nm was proven by the following procedures:

- Validation of the optical performance (*Section 18 – Performance testing bench*)
- Validation of optical performance after simulation of aging (*Section 18 – Performance testing bench*)

Combining the test results and the shared characteristics it can be concluded that the submitted devices are as safe and as effective as the predicate devices.

5.4 Reprocessing

Reprocessing validation includes the manual cleaning process, the automated cleaning process, and the sterilization process.

The manual and automated cleaning process passed all acceptance criteria.

The validation of the sterilization was performed according to AAMI TIR12, Annex B. The sterility assurance level (SAL) of 10^{-6} was achieved and therefore the sterility of the submitted devices is ensured.

The results proved that the submitted devices are as safe as the predicate device and thus can be deemed substantially equivalent to the predicate device.

5.5 Biocompatibility

The telescopes include components with direct patient contact. Therefore, a biological risk assessment was performed considering the following standards:

- 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

Biological testing and chemical characterization proved that the PANOVIEW Ultra telescopes are as safe as the predicate devices and thus can be deemed substantially equivalent to the predicate device.

5.6 Clinical Performance Testing

No clinical performance testing was performed.

5.7 Non-Clinical Performance Testing

The efficacy and safety of the submitted devices is documented by the verification and validation testing. The testing confirms that the products meet 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, stability testing, and temperature testing according to IEC 60601-2-18. In addition, optical performance was evaluated according to ISO 8600-1/-3/-5 for the submitted devices and parameters were compared to those of the predicate devices to prove equivalence.

It could be shown that the submitted devices function as safe as effective as the predicate device and therefore can be deemed substantially equivalent.

5.8 Conclusions

The PANOVIEW Ultra telescopes have equivalent indications for use as the predicate device. The nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as the legally marketed devices.

Therefore, the submitted telescopes have been deemed to be substantially equivalent to the legally marketed devices.