May 3, 2019

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

Re: K183188
Trade/Device Name: Flexible Sensor-Ureterorenoscopes BOA Vision EF
Flexible Sensor-Ureterorenoscopes COBRA Vision EF
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB, FGA, ODC
Dated: April 9, 2019
Received: April 11, 2019

Dear Mike 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 R. Kreitz -S

for Glenn Bell, Ph.D.
Assistant Division 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
Indications for Use

510(k) Number (if known)
K183188

Device Name
Flexible Sensor-Ureterorenoscopes BOA Vision EF
Flexible Sensor-Ureterorenoscopes COBRA Vision EF

Indications for Use (Describe)
The Flexible Sensor-Ureterorenoscopes BOA Vision EF and Flexible Sensor-Ureterorenoscopes COBRA Vision EF are used for visualizing body cavities and organs via natural and surgically created passages.

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

For examination, diagnostics and/or therapy in conjunction with endoscopic accessories.

The product is used in the following disciplines:

Urology:
- Urogenital tract
- Nephroscopy

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 CORP.
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Phone: (847) 913 1113
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Contact Person: Mr. Michael G. Loiterman
Date Prepared: May 02, 2019

II. DEVICES
Trade Name: Flexible Sensor-Ureterorenoscope BOA VISION EF
Flexible Sensor-Ureterorenoscope COBRA VISION EF

Model numbers: BOA: 73551071, 73551076
COBRA: 73561071, 73561076
Accessories: 15369108, 15394144, 163914, 15023205

Common or Usual Name: Flexible Video Ureterorenoscope, Nephroscope, Endoscope
Channel Accessories

Classification Name: Endoscope and Accessories (21 CFR 876.1500)

Regulatory Class: II

Product Code: FGB (Ureteroscope and Accessories, flexible/rigid)
ODC (Endoscope Channel Accessory)
FGA (Kit, Nephroscope)

III. PREDICATE DEVICE
Flexible Video Uretero Renoscope Flex X (K131369)

This predicate has not been subject to a design-related recall.
5.1 Description
The Flexible Sensor-Ureterorenoscope BOA VISION EF (short name: BOA) and Flexible Sensor-Ureterorenoscopes COBRA VISION EF (short name: COBRA) are flexible video endoscopes used for visualizing body cavities and organs via natural and surgically created passages.

The Flexible Sensor-Ureterorenoscopes compromise a handle and a flexible shaft connected to the handle with an active controlled deflection section at the endoscope tip.

The video image of the Flexible Sensor-Ureterorenoscopes is produced by a CMOS imaging sensor located at the tip of the insertion shaft together with the objective lens. The imaging sensor with the electronics in the handle generates a signal that is transferred to the designated camera controller ENDOCAM Flex HD (cleared with K161204), which processes the signals to display them on a monitor (not part of this submission).

The Flexible Sensor-Ureterorenoscopes use integrated LED lights for illumination.

The Flexible Sensor-Ureterorenoscopes provide a working channel with 1.2 mm diameter and a working length of 680 mm length. A Luer sealing cap may be used to seal the provided Luer connectors if not used.

The Flexible Sensor-Ureterorenoscope COBRA VISION EF has a second separate channel with 0.8 mm diameter for laser fibers or continuous irrigation. The laser fiber channel is equipped with a laser adjustment unit for housing, clamping and aligning the laser fiber, which support to move the clamped laser fiber sensitively by turning an adjustment ring for contacting the stone.

Parts of the Flexible Sensor-Ureterorenoscopes have direct or indirect patient contact. When used as intended, the duration of tissue contact is limited (up to 24 hours). The used raw material with direct or indirect patient contact consist of Stainless steel, optical glass, Polyurethane, Perfluoroalkoxy (PFA) and adhesives (epoxy).

5.2 Indications for Use
The Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF are used for visualizing body cavities and organs via natural and surgically created passages.

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

For examination, diagnostics and/or therapy in conjunction with endoscopic accessories.

The product is used in the following disciplines:
Urology:
  - Urogenital tract
  - Nephroscopy
5.3 Comparison with Predicate Device

The new Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF and the predicate device are optoelectronic devices used for visualizing body cavities and organs via natural and surgically created passages, for diagnostic and therapeutic use on human patients in the urogenital tract and kidney. Thus, the intended use can be declared as same.

The new Flexible Sensor-Ureterorenoscopes BOA VISION EF and Flexible Sensor-Ureterorenoscopes COBRA VISION EF have equivalent technical characteristics and fundamental design as the predicate device. The operating principle, mechanical design, dimensions and device materials are same or equivalent. The submitted devices and the predicate device are delivered non-sterile and must be reprocessed before and after each use.

The small differences between the new Flexible Sensor-Ureterorenoscopes and the predicate device are mainly related to the following aspects:

**Design/Material:**
The Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF with their working channel have similar diameter, length and deflection angle compared to the predicate device. Different material was used for the new Flexible Sensor-Ureterorenoscopes to improve kink characteristics and flexibility of the insertion part and deflectable distal tip tubing.

**Laser fiber channel:**
The Flexible Sensor-Ureterorenoscope COBRA VISION EF provides an additional channel for laser fibers or continuous irrigation. The use of laser fiber and irrigation are possible on the predicate device also through the working channel. The laser fiber channel is equipped with a laser adjustment unit for housing, clamping and aligning the laser fiber, which supports the clamped laser fiber to move sensitively by turning an adjustment ring for contacting the stone. Without the laser adjustment unit, the laser fiber still can be guided manually by the user the same way as it is done in the predicate device.

5.4 Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

**Biocompatibility**
Biological Risk Assessment, considering FDA Guidance -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, was performed and necessary tests were conducted to ensure the biocompatibility of the product.
Considering the categorization of the Flexible Sensor-Ureterorenoscopes as externally communicating devices in limited (≤24h) contact with tissue, the following endpoints were tested according to ISO 10993 standards: Cytotoxicity, Sensitization, Intracutaneous reactivity/irritation, acute systemic toxicity, material mediated pyrogenicity.

This demonstrates the biocompatibility of the Flexible Sensor-Ureterorenoscopes when used as intended.

**Cleaning and Sterilization**
Validation of reprocessing was performed in accordance with the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”, Guidance for Industry and Food and Drug Administration Staff, issued March 17, 2015.

**Electrical safety and Electromagnetic Compatibility**
Richard Wolf’s Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF comply with the standards regarding electrical safety and electromagnetic compatibility:
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbances - Requirements and test

**Photobiological safety**
The used LEDs in submitted Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF were tested according to the following standard:

**Mechanical and Optical Performance**
The Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF were designed to comply with applicable parts of ISO 8600. Optical measurements were performed according to applicable part of ISO 8600 standard.

Mechanical characteristics were tested and include leakage tightness, bending, deflection endurance, withstand of channel.

In addition, comparative testing related to image quality parameters was performed for submitted Flexible Sensor-Ureterorenoscopes and the predicate device to support substantial equivalence.
Software Verification and Validation Testing
The submitted Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF do not contain software.

Animal and Clinical Study
Animal Study and Clinical Study were not performed for submitted products.

5.5 Conclusion
Richard Wolf's Flexible Sensor-Ureterorenoscope BOA VISION EF, Flexible Sensor-Ureterorenoscope COBRA VISION EF and their accessories have the same intended use as the predicate device. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as or better than the legally marketed device. For these reasons, Richard Wolf's Flexible Sensor-Ureterorenoscope BOA VISION EF and Flexible Sensor-Ureterorenoscope COBRA VISION EF and their accessories are substantially equivalent to the legally marketed device.