July 30, 2021

TROKAMED GmbH
Stefan Weiland
Regulatory Affairs Manager
Kleine Breite 17
Geisingen, BW 78187
Germany

Re: K200770
Trade/Device Name: Mini PCNL-System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: June 10, 2021
Received: June 14, 2021

Dear Stefan Weiland:

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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200770

Device Name

Mini PCNL-System

Indications for Use *(Describe)*

The nephroscopy accessory set is intended for minimally invasive procedures in nephroscopy.

The shaft is a reusable, surgically invasive device for shortterm use. It is designed to bring instruments, telescopes, and fluids to the surgical site.

The Dilator is a reusable, surgically invasive device for temporary use. It is designed to widen existing surgically invasive openings.

Patient Target Group
Patients with kidney or upper urinary tract conditions who require a nephroscopic procedure.

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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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 28, 2021

510(k) Summary

Submitted by: TROKAMED GmbH
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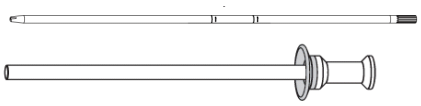
Predicate Device

Manufacturer	510(k) Number	Device Name
RICHARD WOLF Medical Instruments Corporation	K994223	Nephroscope Set

Comparison of Technological Characteristics with the Predicate Device

Description	Subject device	Predicate Device (K994223)
Picture of the device		
Design of dilator	Cannulated, two lumens	Cannulated
Design of shaft	Round, without irrigation tap, meatus ring, distal end straight	Round, fixed irrigation tap, distal end straight
Material of the shaft	Stainless steel, plastic	Titanium, stainless steel, plastic
Material of dilator	Stainless steel	Stainless steel
Lumen/Inner diameter of the dilator	1 mm, 1mm; 1 mm, 1.3 mm	4 mm; 5 mm
Outer diameter of the dilator	15 Fr.; 17 Fr.	12 Fr.; 15 Fr.
Wall thickness	0.5 mm	0.25 mm
Working length of the dilator	370 mm	320 mm
Outer diameter of the sheath	18 Fr., 20 Fr.	18 Fr.
Working length of the sheath	130 mm; 160 mm	150 mm
Device packaged as sterile	No	No
Requires sterilization prior to use	Yes	Yes
Single-Use/Reusable	Reusable	Reusable
Sterilization method	Steam sterilization	Moist Heat or Steam Sterilization Ethylene Oxide Hydrogen Peroxide

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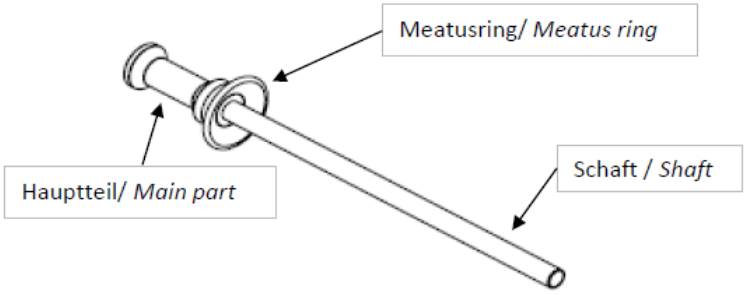
Subject Device Description

Trade Name:	Mini PCNL-System
Common Name:	Endoscopic Access Overtube, Gastroenterology-Urology
Classification Name:	Endoscope and accessories (21 CFR 876.1500)
Product code:	FED (Endoscopic Access Overtube, Gastroenterology-Urology)

The TROKAMED GmbH Mini PCNL-System consists of shaft and dilator. The diameter is specified directly on the shaft and dilator. This ensures that the instrument can be assigned easily and only suitable components are used. The instruments cannot be disassembled. The puncture channel is expanded with the dilator at the beginning of surgery. The procedure, during which kidney stones can be destroyed, is then performed via the shaft. The kidney stones are automatically transported out of the proximal end of the shaft as a result of the cleaning pressure and by the irrigation fluid. The nephroscope may not be fully mounted on the shaft here.

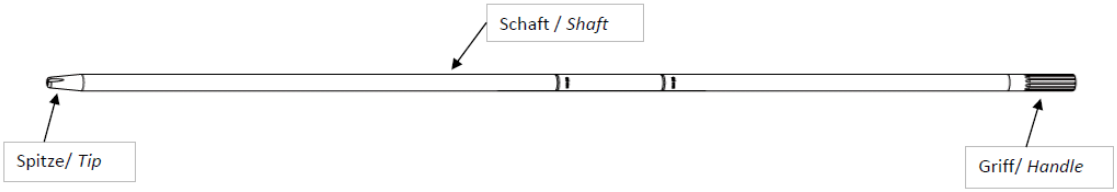
Shafts

The nephroscopic shafts are rigid reusable instruments with inner lumen and are used as an introducer for the instrument into the surgical site. The shaft itself is introduced into the surgical site by the help of the dilator.
Example WA2PS20S:



Dilators

The dilators are rigid reusable instruments. They are equipped with two lumens: one lumen in the center and one on the side. The guide wire (not included in this submission) is fed through the medial lumen. An additional safety wire (not included in this submission) can be guided through the lateral lumen. Markings indicate when the conical tip of the dilator is protruding from the shaft. Both types of dilators has the same total and working length, but different diameters.
Example: WA2PD20A:



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The Mini PCNL-System is used together with a suitable nephroscope. The nephroscope is not part of the subject device and not included in this submission.

The Mini PCNL-System is delivered in non-sterile conditions and has to be processed before using it for the first time and before each use afterwards.

The following table identifies all models included in this submission:

Article Number	Description	Key components	Material	Product Dimensions
WA2PS18S	Shaft, 18 Fr.	Main part, Meatus ring, Shaft	1.4301 PPSU 1.4301	Total length: 165 mm Working length: 130 mm Outer Ø: 18 Fr Inner Ø: 15 Fr
WA2PS18L	Shaft, 18 Fr.	Main part, Meatus Ring, Shaft	1.4301 PPSU 1.4301	Total length: 195 mm Working length: 160 mm Outer Ø: 18 Fr Inner Ø: 15 Fr
WA2PS20S	Shaft, 20 Fr.	Main part, Meatus Ring, Shaft	1.4301 PPSU 1.4301	Total length: 165 mm Working length: 130 mm Outer Ø: 20 Fr Inner Ø: 17 Fr
WA2PS20L	Shaft, 20 Fr.	Main part, Meatus Ring, Shaft	1.4301 PPSU 1.4301	Total length: 195 mm Working length: 160 mm Outer Ø: 20 Fr Inner Ø: 17 Fr
WA2PD18A	Dilator, 15 Fr., (to be used with WA2PS18S, WA2PS18L)	Handle, Shaft Tip	1.4301 1.4301 1.4301	Total length: 390 mm Working length: 370 mm Outer Ø: 15 Fr Inner Ø: 3 Fr, 3 Fr
WA2PD20A	Dilator, 17 Fr., (to be used with WA2PS20S, WA2PS20L)	Handle, Shaft Tip	1.4301 1.4301 1.4301	Total length: 390 mm Working length: 370 mm Outer Ø: 17 Fr Inner Ø: 3 Fr, 4 Fr

Table 1: Information about subject device

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Indications for Use

The nephroscopy accessory set is intended for minimally invasive procedures in nephroscopy.
The shaft is a reusable, surgically invasive device for shortterm use. It is designed to bring instruments, telescopes, and fluids to the surgical site.
The Dilator is a reusable, surgically invasive device for temporary use. It is designed to widen existing surgically invasive openings.

Patient Target Group:
Patients with kidney or upper urinary tract conditions who require a nephroscopic procedure.

Comparison of Indications for Use with Predicate Device

Indications for Use Predicate Device:
The nephroscope, with its accessories, is used, with suction for the disintegration and removal/extraction of kidney and bladder stones. The stones are removed, under endoscopic control, through percutaneous or transurethral passages, in conjunction with intercorporeal pneumatic, ultrasound, electrohydraulic or laser lithotripters.

We state that the Indications for Use are the same for the subject and the predicate device because both are used in the percutaneous treatment of renal calculi and are to be controlled by endoscopes during surgery.

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Non-Clinical Performance Testing
(only the non-clinical studies used for the determination of the substantial equivalence (SE) of the subject device to the predicate device)

Tests	Standard Reference to Tests	Results
Reprocessing Reprocessing Study 194101-45, 02 AUG 2019 (Worst Case principle)	**EN ISO 17664 / ANSI AAMI ISO 17664: 2017**, Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices. **AAMI TIR30: 2011** (reapproved 2016), A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. **ANSI/AAMI ST79: 2017**, Comprehensive guide to steam sterilization and sterility assurance in health care facilities. **ASTM E2314: 2003** (reapproved 2014), Standard test method for determination of effectiveness of cleaning processes for reusable medical instruments using a microbiologic method (simulated use test). **ASTM F3208: 2018**, Standard Guide for selecting test soils for validation of cleaning methods for reusable medical devices. **ASTM E1766: 2015**, Standard test method for determination of effectiveness of sterilization processes for reusable medical devices. **ANSI/AAMI ST67: 2011** (reapproved 2017), Sterilization of health care products – Requirements and guidance for selecting a sterility assurance level (SAL) for products labelled „sterile“. **FDA guidance**: 2015/2017, Reprocessing Medical Devices in Health Care Settings – Validation Methods and Labelling.	Summarizing the results of improved protein test and indirect microbial test, a sufficient ability of the tested master Worst Case products for an effective cleaning can be stated. All tested products showed a sufficient spore log reduction (SLR > 12) by use of standard sterilization parameters. Therefore, a sufficient ability of the tested master Worst Case products for an effective steam sterilization can be stated.
Life Expectancy Testing: FB-15_02_001_TR_Mini PCNL_01_mechanical test_15Sep2020 (Subject device tested)	TROKAMED standard FB-26_07_010_Product Life expectancy TROKAMED Standard Operating Procedures	Material durability and functionality are verified for the given lifetime. (Worst Case principle) Mechanical strength test with unaged and aged subject device.

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Tests	Standard Reference to Tests	Results
Biocompatibility Evaluation: - Evaluation of basic biological assessment - 091924-20 "Cytotoxicity, L929-Proliferation" - 091925-20 "chemical analysis (characterizations of organic release products)" (Worst Case principle)	**ISO 10993-1:2018** Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process **ISO 10993-5:2009** Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity **ISO 10993-10: 2010** Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization **ISO 10993-12:2012** Biological evaluation of medical devices Part 12: Sample preparation and reference materials **ISO 10993-18:2020** Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process **FDA blue book memorandum (#G95-1)**	A cytotoxicity testing of Worst Case AUF11020 has verified that no substances of cell toxic concentration are released. The chemical characterization has shown that solvable substances or degradation products of Worst case AUF11020 do not exceed the toxicological relevant concentrations.
Mechanical Testing: - 2006-02-06_UB_Tensile tests with tubes_english (Worst Case principle)	none (TROKAMED Standard Operating Procedures only)	Summary of bending and breaking forces of stainless steel TROKAMED instruments.
- 2014-09-23 Bending load of the shaft tubes English_10Jun2021 (Worst Case principle)	none (TROKAMED Standard Operating Procedures only)	Shaft of subject device withstands maximal loading forces within minimally invasive surgery.
- FB-15_02_001_TR_Mini PCNL_01_mechanical test_15Sep2020 (Subject device tested)	none (TROKAMED Standard Operating Procedures only)	Stability and strength of connecting points of the subject device, unaged and aged.

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Reprocessing
The TROKAMED Mini PCNL-System is covered by the reprocessing validation (Worst Case principle) of study 194101-45 (02 AUG 2019, accredited laboratory Medical Device Services) including manual and automated cleaning before steam sterilization. Both, the subject and the predicate device are reusable, non-sterile instruments that have to be reprocessed by manual and automated cleaning before steam sterilization after receipt by the end user (before the first and after each subsequent use).

Life Expectancy Testing:
General product lifetime is according to 1.4301/ 304 instruments listed in document "FB-26_07_010_Product Life expectancy", nephroscopic instruments: these instruments are exposed to very low mechanical stress during minimally invasive surgery. Material durability, labeling and functionality are verified for the given lifetime. To test mechanical resistance, unaged and aged subject devices have been used and no difference between them was recognizable.

Biocompatibility
The biocompatibility of the device components has been stated in TROKAMED's biological assessment (Worst Case principle, Biocompatibility 2021-06-08, cytotoxicity, sensitization and irritation tests performed by accredited laboratories eurofins Medical Device Testing and Medical Device Services). The biological assessment is based on a Worst Case principle with a sample instrument (AUF11020) covering the subject device in all aspects of biocompatibility. The tests confirm that the materials used are biocompatible, separately as well as combined in the final subject device and including possible manufacturing contamination and residues, No potentially dangerous interactions or consequences have been identified if there is short termed contact to tissue, biological cells and body fluids of the human body.

Mechanical Testing:
Mechanical Test Report "2006-02-06_UB_Tensile tests with tubes_english" (Worst Case principle) lists details of tensile tests with TROKAMED shafts according to length and wall thickness, covering the dimensions of the subject device.
Mechanical Test Report "2014-09-23 Bending load of the shaft tubes English_10Jun2021" (Worst Case principle) shows that mechanical safety of the TROKAMED tube shaft instruments made of 1.4301/ 304 (welded and cold redrawn several times) based on strength of the tube material is given. The tested tube shaft instruments show that the TROKAMED shafts and dilators withstand the forces during application in minimally invasive surgery.
Mechanical Test Report "FB-15_02_001_TR_Mini PCNL_01_mechanical test_15Sep2020" (subject device tested) is to show that the stability and strength of the connecting points of the subject device are solid enough for the forces applied during regular application according to the intended use. A cumulative simulation of processing had been performed. When used as intended, mainly axial forces occur. If at all, only very small lever forces occur in practice, which neither influence nor endanger the strength of the welded joints, nor the stability and dimensional stability of the instrument itself.
A comparison of technological characteristics between subject and predicate device shaft show that with comparable length and diameter, the wall thickness is 0.5 mm on the subject device compared to 0.25 mm on the predicate device. As a result, the mechanical stability of the subject device is at least the same as of the predicate device. The dilators are equivalent as well: the subject device has a larger working length (370 mm to 320 mm) but the larger outer diameter (4.9 mm to 4.0 mm) equalizes the mechanical stability.

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Conclusion

The Mini PCNL-System has the same intended use and the same major design and technical characteristics as the predicate device.
The results of the non-clinical performance tests demonstrate that the subject device is as safe and effective as the predicate device.
Overall, the subject device is equivalent to the predicate device.