April 29, 2022

Auris Health, Inc.
Angela Wong
Staff Regulatory Affairs Analyst
150 Shoreline Drive
Redwood City, CA 94065

Re: K213334
Trade/Device Name: Monarch® Platform, Urology
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB, LJH
Dated: March 25, 2022
Received: March 29, 2022

Dear Angela Wong:

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)*
K213334

Device Name
Monarch® Platform, Urology

Indications for Use *(Describe)*
The Monarch® Platform, Urology, the Ureteroscope, and endourology accessories are indicated to provide endoscopic visualization and access of organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) with transurethral access or transurethral access in conjunction with percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

## 1) General Information

| | |
|---|---|
| **510(k) Submitter** | Auris Health, Inc., a Johnson and Johnson Family Company<br>150 Shoreline Drive<br>Redwood City, CA 94065 |
| **FDA Registration Number** | 3014447948 |
| **Primary Correspondent** | Angela Wong<br>Staff Regulatory Affairs Specialist<br>Auris Health, Inc., a Johnson and Johnson Family Company |
| **Contact Information** | Email: lwong6@its.jnj.com<br>Phone: (408) 613-9734 |
| **Date Prepared** | March 25th, 2022 |

## 2) Device Identification

The ***Monarch® Platform, Urology*** consists of Monarch® Tower, Monarch® Cart, Monarch® Fluidics Pump, Monarch® Controller, Monarch® Ureteroscope and endourology instruments and accessories needed to perform Monarch® Urology diagnostic and therapeutic procedures. The ***Monarch® Platform, Urology*** can be identified as follows:

| | |
|---|---|
| **Proprietary Name:** | ***Monarch® Platform, Urology*** |
| **Device Classification Name:** | Ureteroscope and Accessories, Flexible/Rigid |
| **Regulation Description:** | Endoscope and Accessories |
| **Regulation Number:** | 876.1500 |
| **Device Class** | Class II |
| **Product Code:** | FGB, LJH |

Devices bundled within the **Monarch® Platform, Urology** and its instruments and accessories can be identified as follows:

**a)**

| | |
|---|---|
| **Proprietary Name:** | ***Monarch® Fluidics Pump*** |
| **Device Classification Name:** | System, Irrigation, Urological |
| **Regulation Description:** | Urological Catheter and Accessories |
| **Regulation Number:** | 876.5130 |
| **Device Class** | Class II |
| **Product Code:** | LJH |

b)

| | |
|---|---|
| **Proprietary Name:** | ***Monarch® Mini-PCNL Suction Catheter*** |
| **Device Classification Name:** | Needle, Catheter |
| **Regulation Description:** | Introduction/drainage catheter and accessories |
| **Regulation Number:** | 878.4200 |
| **Device Class** | Class I |
| **Product Code:** | GCB |

c)

| | |
|---|---|
| **Proprietary Name:** | ***Dilation Set*** |
| **Device Classification Name:** | Catheter, Nephrostomy |
| **Regulation Description:** | None |
| **Regulation Number:** | None |
| **Device Class** | Unclassified |
| **Product Code:** | LJE |

d)

| | |
|---|---|
| **Proprietary Name:** | ***Percutaneous Sheath*** |
| **Device Classification Name:** | Kit, Nephroscope; Catheter, Nephrostomy |
| **Regulation Description:** | Endoscope and Accessories; None |
| **Regulation Number:** | 876.1500, None |
| **Device Class** | Class II, Unclassified |
| **Product Code:** | FGA, LJE |

### 3) Predicate Devices

| | |
|---|---|
| **Proprietary Name:** | ***LithoVue System*** |
| **Device Classification Name:** | Ureteroscope and Accessories, Flexible/Rigid |
| **Regulation Description:** | Endoscope and Accessories |
| **510(k) Number:** | K153049 |
| **Regulation Number:** | 876.1500 |
| **Device Class** | Class II |
| **Product Code:** | FGB |

| | |
|---|---|
| **Proprietary Name:** | ***Karl Storz Uromat E.A.S.I.*** |
| **Device Classification Name:** | System, Irrigation, Urological |
| **Regulation Description:** | Urological Catheter and Accessories |
| **510(k) Number:** | K162992 |
| **Regulation Number:** | 876.5130 |
| **Device Class** | Class II |
| **Product Code:** | LJH |

| | |
|---|---|
| **Proprietary Name:** | ***LithAssist Suction Control for Laser Lithotripsy*** |
| **Device Classification Name:** | NA |
| **Regulation Description:** | NA |
| **510(k) Number:** | 510(k) Exempt |

| | |
|---|---|
| **Regulation Number:** | NA |
| **Device Class** | NA |
| **Product Code:** | NA |

| | |
|---|---|
| **Proprietary Name:** | ***Amplatz Renal Dilator Kit*** |
| **Device Classification Name:** | Catheter, Nephrostomy |
| **Regulation Description:** | Unclassified |
| **510(k) Number:** | K172527 |
| **Regulation Number:** | None |
| **Device Class** | Class II |
| **Product Code:** | LJE |

| | |
|---|---|
| **Proprietary Name:** | ***Richard Wolf Nephroscope Set*** |
| **Device Classification Name:** | Kit, Nephroscope |
| **Regulation Description:** | Endoscope and accessories |
| **510(k) Number:** | K994223 |
| **Regulation Number:** | 876.1500 |
| **Device Class** | Class II |
| **Product Code:** | FGA |

| | |
|---|---|
| **Proprietary Name:** | ***Amplatz Type Renal Sheaths*** |
| **Device Classification Name:** | Catheter, Nephrostomy |
| **Regulation Description:** | None |
| **510(k) Number:** | K172929 |
| **Regulation Number:** | None |
| **Device Class** | Unclassified |
| **Product Code:** | LJE |

In compliance with *Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* we are including the following as reference devices:

| | |
|---|---|
| **Proprietary Name:** | ***Monarch Platform*** |
| **Device Classification Name:** | Bronchoscope (Flexible or Rigid) |
| **Regulation Description:** | Bronchoscope (Flexible or Rigid) And Accessories |
| **510(k) Number:** | K193534 |
| **Regulation Number:** | 21 CFR 874.4680 |
| **Device Class** | II |
| **Product Code:** | EOQ |

| | |
|---|---|
| **Proprietary Name:** | ***FluidSmart*** |
| **Device Classification Name:** | Insufflator, Hysteroscopic |
| **Regulation Description:** | Hysteroscopic Insufflator |
| **510(k) Number:** | K172048 |

| | |
|---|---|
| **Regulation Number:** | 21 CFR 884.1700 |
| **Device Class** | II |
| **Product Code:** | HIG, LGZ, HRX |

| | |
|---|---|
| **Proprietary Name:** | ***Karl Storz Flexible Video-Uretero-Renoscope System*** |
| **Device Classification Name:** | Ureteroscope and Accessories, Flexible/Rigid |
| **Regulation Description:** | Endoscope and accessories |
| **510(k) Number:** | K141250 |
| **Regulation Number:** | 21 CFR 876.1500 |
| **Device Class** | II |
| **Product Code:** | FGB |

## 4) Device Description

The **Monarch® Platform, Urology** ("Proposed Device") is a capital equipment platform that enables electro-mechanical articulation and precise control of a flexible ureteroscope and/or a flexible suction catheter for visualization and access to the urinary tract for diagnostic and therapeutic procedures. The ureteroscope and suction catheter move only under continuous and direct physician control, via the Monarch Controller.

The proposed device consists of Monarch® Tower, Monarch® Cart, Monarch® Fluidics Pump, Monarch® Software, Monarch® Controller, Monarch® Ureteroscope and endourology instruments and accessories needed to perform Monarch Urology diagnostic and therapeutic procedures. The device as well as its instruments and accessories are used together during urological diagnostic and therapeutic procedures and are bundled in this 510(k) submission so they can be addressed during one review. The summary descriptions of each component are outlined below.

**Monarch® Tower:** The Monarch® Tower (Tower) contains the primary procedural display interface for the physician that is provided by a touchscreen monitor for physician viewing and computers running the Monarch software. The monitor has a touchscreen and allows for user input during setup and intra-operative use. The tower has integrated electromagnetic (EM) tracking and video signal processing components. In addition, the tower provides connectivity for the endoscope camera as well as the fluidics pump.

**Monarch® Cart:** The Monarch® Cart (Cart) contains a touchscreen, three robotic arms and electronic systems required to power and operate the robotic arms. The Cart touchscreens accepts user input and shows instructions for arm deployment and cart functions. The robotic arms possess multiple degrees of freedom. The cart transmits the physician directed movement to the Ureteroscope and other instruments during a procedure.

**Monarch® Fluidics Pump:** The Monarch® Fluidics Pump (Fluidics Pump) controls the irrigation and suction during a procedure. The Fluidics Pump is connected to the Monarch Tower via an umbilical cable allowing electrical and data communication. The Fluidics Pump

provides the physician with the ability to control irrigation and suction levels during a procedure. The Urology Irrigation Cartridge and Suction Set are irrigation and suction tubing provided as sterile accessories to connect the Fluidics Pump to the Ureteroscope and Instruments during ureteroscopy or PCNL procedures.

**Monarch® Software:** The Monarch® Software provides the user with the ability to safely drive the Monarch® Ureteroscope and Monarch® Mini-PCNL suction catheter around the kidney and within the calyces of interest as well as provides optional navigation guidance to the user to insert the needle to the target during Monarch® PCNL procedure. It receives user input from the Monarch® Controller, computes the appropriate robotic motion to coordinate the movement of the robotic arms and endoscopic devices loaded onto the Cart. It provides a graphical user interface where the endoscopic camera view is shown in real time and displays important system status information.

**Monarch® Controller:** The Monarch® Controller (Controller) is a handheld device that serves as the user interface that allows the physician to control the system during a procedure. An Umbilical cord connects the Controller to the Tower.

**Monarch® Ureteroscope**: The Monarch® Ureteroscope (Ureteroscope) is comprised of an endoscope that provides vision, illumination, and a working channel to the distal tip of the device. The Ureteroscope can be navigated by the user within the bladder, urinary tract, and kidney. It contains a working channel to accommodate compatible commercially available working channel instruments. The Ureteroscope can be articulated 2-directions (along a single plane) when manually driven or can be articulated 4-directions (along two planes) when mounted to the electromechanical arms under command by the physician using the endoscopic controller. The shaft of the ureteroscope can also be rolled 155° in either direction to reorient the camera and working channel. The Ureteroscope is packaged within the Monarch® Ureteroscopy Kit. The Monarch® Ureteroscopy Kit also includes Ureteroscope Valve, Ureteroscope Driver and Laser Driver (accessories for Ureteroscopy procedure).

Procedural specific instruments and accessories for the proposed device are outlined below, these devices are single-use devices and sterilized via EO.

- **Monarch® Mini-PCNL Suction Catheter:** The Monarch® Mini-PCNL Suction Catheter (Suction Catheter) is part of the Monarch® Mini-PCNL Kit. The Suction Catheter is a flexible device that is inserted into the kidney via antegrade tract under direct visualization from the ureteroscope. It has a center lumen which allows for the suction of stone debris and can articulate in 4 directions. The suction catheter is manipulated by one robotic arm under the control of a physician who is concurrently controlling the Ureteroscope.

- **Dilation Set:** The Dilation Set is part of the Monarch® Mini-PCNL Kit. The Dilation Set includes:
    - 8Fr dilator
    - 10Fr catheter
    - Percutaneous Sheath Dilator

The 8Fr dilator and 10 Fr catheter are constructed of PTFE. The Percutaneous Sheath Dilator is 21Fr and has a lumen sized to fit over the 8Fr dilator. The Percutaneous Sheath Dilator is used to dilate the percutaneous tract to 18 Fr to accommodate the Percutaneous Sheath.

- **Percutaneous Sheath**: The Percutaneous Sheath is part of the Monarch® Mini-PCNL Kit. The Percutaneous Sheath consists of an inner metal sheath with a threaded connection and a metal outer sheath. It is designed to establish percutaneous access and designed to allow simultaneous irrigation and suction of fluid to support removal of kidney stones. The outer sheath has a molded hub with an angled luer connection for irrigation and an insertion depth marking on the distal end.

## 5) Intended Use/Indications for Use

**Intended Use:**

The **Monarch® Platform, Urology** and its accessories are intended to access and visualize anatomical locations within the urinary tract and interior of the kidney of adolescents and adults, aged 12 and up, for diagnostic and therapeutic procedures with transurethral access or transurethral access in conjunction with percutaneous access.

**Indications for Use:**

The **Monarch® Platform, Urology**, the Ureteroscope, and endourology accessories are indicated to provide endoscopic visualization and access of organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) with transurethral access or transurethral access in conjunction with percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

## 6) Comparison of Indication for Use Statement

| Comparison Criteria | Proposed Device<br>Monarch® Platform, Urology | Predicate Device<br>LithoVue System<br>(K153049) | Comparison Assessment |
|---|---|---|---|
| **Indications for Use** | The **Monarch® Platform, Urology**, the Ureteroscope, and endourology accessories are indicated to provide endoscopic visualization and access of organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) with transurethral access or transurethral access in conjunction with percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract. | The LithoVue System is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract. | **Similar to Predicate**<br><br>**Note:** Both devices provide access to urinary tract and interior of the kidney through transurethral and percutaneous routes to perform various diagnostic and therapeutic procedures in the urinary tract. In addition, the **Monarch® Platform, Urology** includes a percutaneous access route that uses Monarch instruments and accessories to facilitate PCNL procedure. These instruments fall within the indication for use of accessing the kidney through percutaneous access routes when used in conjunction with endoscopic accessories as |

| Comparison Criteria | Proposed Device<br>Monarch® Platform, Urology | Predicate Device<br>LithoVue System<br>(K153049) | Comparison Assessment |
|---|---|---|---|
| | | | cleared in the predicate's indication for use statement. |

## 7) Comparison of Technological Characteristics with the Predicate and Reference Device

Overall, the proposed device, predicate and reference devices are based on the following similar basic technological elements:

- Device provides real-time images to the physicians to facilitate diagnostic and therapeutic procedures in the urinary tract and interior of the kidney.
- Device provides access to urinary tract and interior of the kidney through transurethral and percutaneous routes.
- Device contains a flexible ureteroscope to visualize and gain access to the urinary tract and interior of the kidney.
- Device requires continuous direct control by physician user to move the ureteroscope.
- Device movement is only at the command of the physician.
- Device moves the distal tip by pulling wires.
- Device (ureteroscope) contains a working channel to allow delivery of the lithotrite and stone retrieval basket.
- Ureteroscope working channel size is identical to the predicate to allow the use of commercially available lithotrites.
- Ureteroscope dimensions and image specifications are comparable between the subject and predicate ureteroscopes.

The main difference between the proposed device and the primary predicate, **LithoVue Systems (K153049)**, is that the LithoVue Systems lacks the electromechanical control mechanism. For this reason, the following reference devices are being added for their similarities in technological characteristics as compared to the proposed device.

| Reference Device | Name and 510(k) Number | Technological Characteristics Comparison |
|---|---|---|
| Reference Device 1 | Monarch Platform (Bronchoscopy Indication)<br>(K193534) | Identical electromechanical control mechanism and optional electromagnetic navigation technological characteristics. |
| Reference Device 2 | Karl Storz Flexible Video-Uretero-Renoscope System<br>(K141250) | Similar in performance specification as compared to Monarch Ureteroscope. |

The LithoVue Systems also lacks the suction and irrigation functionality included within the proposed device provided via the **Monarch® Fluidics Pump**. For this reason, the following predicate and reference devices are being added for their similarities in technological characteristics as compared to the **Monarch® Fluidics Pump**.

| Predicate/ Reference Device | Name and 510(k) Number | Technological Characteristics Comparison |
|---|---|---|
| Predicate Device | Karl Storz Uromat E.A.S.I (K162992) | Identical suction and irrigation functionality as compared to the **Monarch® Fluidics Pump**. |
| Reference Device | FluidSmart (K172048) | Similar in control mechanism, performance specification and fluid warming capabilities as compared to the **Monarch® Fluidics Pump**. |

Comparison of technological characteristics with the Predicate Device for devices bundled within the instruments and accessories kit of the **Monarch® Platform, Urology** are described below:

| Proposed Device | Predicate/ Reference Device | Name and 510(k) Number | Technological Characteristics as Comparison |
|---|---|---|---|
| **Monarch® Mini-PCNL Suction Catheter** | Predicate | LithAssist Suction Control for Laser Lithotripsy (510(k) Exempt) | **Identical Characteristics:**<br>• Functionality: To provide suction during lithotripsy.<br>**Differences:**<br>• Different size for improved suction of stone fragments.<br>• Electromechanical control of the catheter after manual insertion. |
| **Dilation Set** | Predicate | Amplatz Renal Dilator Kit (K172527) | **Identical Characteristics:**<br>• Functionality: To establish dilation of the percutaneous tract to allow for placement of a sheath.<br>**Differences:**<br>• Minor dimensional differences in working length and dilator outer diameter.<br>• Minor differences in material |
| ***Percutaneous Sheath** | Primary Predicate | Richard Wolf Nephroscope Set (K994223) | **Identical Characteristics:**<br>*Functionality: To provide irrigation/aspiration to support removal of kidney stone.<br>**Differences:**<br>• Minor dimensional differences in working length and sheath diameter.<br>• Minor differences in material |

| Proposed Device | Predicate/ Reference Device | Name and 510(k) Number | Technological Characteristics as Comparison |
|---|---|---|---|
| | Secondary Predicate | Amplatz Type Renal Shealths<br>(K172929) | **Identical Characteristics:**<br>*Functionality: To establishing percutaneous access<br><br>**Differences:**<br>• Minor dimensional differences in working length and sheath diameter.<br>• Minor differences in material |

*The **Percutaneous Sheath** has two functionalities: 1) To provide irrigation/aspiration to support removal of kidney stones and 2) To establish percutaneous access.

## 8) Performance Data

The **Monarch® Platform, Urology** was tested for performance in accordance with internal design specification with the applicable performance standards to demonstrate safety and effectiveness. The testing identified no new issues of safety or effectiveness. The testing performed are summarized below:

| Test Name | Description | Results |
|---|---|---|
| Reprocessing, Sterility and Shelf Life | **Reprocessing:**<br><br>The cleaning and disinfection instructions provided in labeling for non-disposable components were validated against the following standards:<br><br>• ***AAMI TIR-12:2020*** *- Designing, Testing, And Labeling Medical Devices Intended for Processing by Health Care Facilities: A Guide For Device Manufacturers*<br>• ***AAMI TIR 30:2011*** *- A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*<br><br>**Sterility:**<br><br>Single-use disposable sterile (EO) devices were validated in accordance with the following standard:<br><br>• ***ISO11135:2014*** *- Sterilization of health care products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.* | Pass |

| Test Name | Description | Results |
|---|---|---|
| | EO residual has been evaluated per:<br>• ***ISO10993-7:2008/And-1:2019*** *- Biological Evaluation of medical devices - Part 7: Ethylene Oxide Sterilization Residuals*<br>**Shelf Life and Sterile Barrier Packaging:**<br>The shelf life and sterile barrier packaging of the single-use disposable devices were evaluated per the following Standards:<br>• ***ISO 11607-1:2019*** *- Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*<br>• ***ASTM F1980 – 16*** *- Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*<br>• ***ASTM F88/F88M-15*** *- Standard Test Method for Seal Strength of Flexible Barrier Materials*<br>• ***ASTM F1886/F1886M-16*** *- Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*<br>• ***ASTM F2096 – 19*** *- Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*<br>**Shipping and Distribution for Single Use Device:**<br>• ***ASTM D4332-14*** *- Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.*<br>• ***ASTM D4169-16*** *- Standard Practice for Performance Testing of Shipping Containers and Systems* | |
| Biocompatibility | The final finished form of the subject device has been used for the biocompatibility evaluation.<br>Biocompatibility for direct and indirect body contacting component has been evaluated in accordance with the provision of the following FDA Guidance document:<br>• *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard* | Pass |

| Test Name | Description | Results |
|---|---|---|
| | *ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*<br><br>Biocompatibility has been validated per the following standards:<br>• ***ISO 10993-1:2018*** *- Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*<br>• ***ISO 10993-5:2009*** *- Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*<br>• ***ISO 10993-6:2016*** *- Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation*<br>• ***ISO 10993-10:2010*** *- Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization*<br>• ***ISO 10993-11:2017*** *- Biological evaluation of medical devices - Part 11: Tests for systemic toxicity* | |
| Electrical Safety and EMC | The proposed device has been fully evaluated for electrical safety and EMC compliance to the following standards:<br>• ***ANSI AAMI ES60601-1:2005 + A2(R)2012 + A1*** *- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)*<br>• ***IEC 60601-1-2:2014*** *- General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*<br>• ***IEC 60601-2-18 2009*** *- Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment* | Pass |
| Software | Software was developed, tested, and verified per the following FDA guidance document:<br>• *Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* | Pass |

| Test Name | Description | Results |
|---|---|---|
| | Results of verification and validation testing confirm that the proposed device conforms to design specifications and meets the needs of the intended users. | |
| Verification Testing | System Level Tests were executed to verify the overall functionality of the proposed device to operate as specified by the design input requirements including workflow, latency, ureteroscope and working channel instruments driving and controls, various functional safety features, and other general functionality. Sub-system level requirements for safety and efficacy of the system, including but not limited to the adherence to regulatory standards were verified. Results of verification testing confirm that the proposed device conforms to design specifications and meets the needs of the intended users. The device met all applicable design input requirements, satisfied all sub-system specifications, and exhibit the electrical, mechanical and functional integrity necessary. | Pass |
| Design Validation | Design Validations were conducted via live porcine model to evaluate the proposed device under simulated use conditions to validate the user needs, including the safety and effectiveness of the system as per its intended clinical use. All intended user needs evaluated met their acceptance criteria. Data collected demonstrated that the proposed device performed in conformance with its intended use and that the intended users were able to perform the procedure as intended. | Pass |
| Human Factors and Usability | Human factors and usability evaluation was performed in accordance with FDA guidance:<br>• *Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices*<br>This evaluation assessed the proposed device for safety and effective use by representative users during a simulated use of Monarch Ureteroscopy and Monarch mini-PCNL procedures after training on using the proposed device in | Pass |

| Test Name | Description | Results |
|---|---|---|
| | the intended environment. Based on the results of the Human Factors and Usability Test, the proposed device has been found to be safe for the intended use by the intended users in the intended environment. | |
| Acute Animal Safety | Acute animal safety studies were executed to demonstrate the capability of the proposed device to safely facilitate renal diagnostic and therapeutic procedures via the transurethral access route and percutaneous access route in a live animal model with relevant anatomy. | Pass |

## 9) Conclusion

Based on the indication for use, technological characteristic, performance testing and comparison to the predicate and reference devices, the **Monarch® Platform, Urology** raises no new questions of safety and effectiveness as compared to the predicate devices and is substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.