June 1, 2023

NDR Medical Technology Pte. Ltd.
℅ Ainoa Forteza
Vice Director of Regulatory Affairs
Alira Health
Avinguda Josep Tarradellas, 123 (7th Floor)
Barcelona 08029
SPAIN

Re: K230185
Trade/Device Name: ANT-X System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB
Dated: May 5, 2023
Received: May 5, 2023

Dear Ainoa Forteza:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
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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)*
K230185

Device Name
ANT-X System

Indications for Use *(Describe)*
The ANT-X System is indicated for use in conjunction with fluoroscopy imaging in percutaneous nephrolithotomy (PCNL) procedures to aid in needle positioning and alignment process.

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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K230185

**510(k) Summary**
**for the ANT-X System**
**(per 21CFR 807.92)**

**Date: May 5, 2023**

**1. 510K Applicant / Submitter:**

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**2. Submission Contact Person**

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**3. Subject Device**

Name of Device: ANT-X System
Common or Usual Name: Robotic Needle Positioning Unit
Classification Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1650
Regulatory Class: II
Product Code: OWB

**4. Predicate and Reference Device**

Predicate Device:
Device Name: Nuvasive LessRay with Enhanced Tracking
510(k) Number: K170800
Classification Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1650
Regulatory Class: II
Product Code: OWB

Reference Device:
Device Name: iSYS 1
510(k) Number: K131433
Classification Name: Computed tomography x-ray system
Regulation Number: 892.1750
Regulatory Class: II
Product Code: JAK

**5. Device Description:**

The ANT-X System is an automated needle positioning medical device that is used in conjunction with fluoroscopy to support percutaneous interventions (PCNL). There are 4 main components to the system – the ANT-X Device, ANT-X Controller Box, ANT- X Needle Holder, and ANT-X Software. It is intended to be used in an operating theatre equipped with standard surgical equipment which are generally found in operating rooms.

The ANT-X Device holds a sterile, disposable needle-guide kit, the ANT-X Needle Holder. The main bulk of ANT-X Device is made of biocompatible polyetheretherketone (PEEK) material. PEEK is preferred to build the robot because it is radiolucent and lightweight while being able to provide relatively high material strength. The Device has a fixed base made of three pairs of high stiffness parallel linkages. The linkages allow millimetric planar needle adjustment. The targeted insertion point will act as a pivot point for the needle. The device will be mounted onto the operating table with a 6-DOF instrument holder (FISSO Articulated arm) such that it can be precisely oriented to the area of interest on the patient.

The ANT-X Controller Box powers the ANT-X Device and is the integrating point for the whole ANT-X System. Images from the C-arm fluoroscopy machine will be passed into the ANT-X Controller Box and then to the ANT-X Software, in real-time. The user will then use the ANT-X Software to command the ANT-X Device to commence needle alignment between the chosen insertion point on the skin surface, and the desired target point within the body. Validation of the puncture trajectory and the final needle insertion will be performed by the surgeon.

Accessory:
The FISSO Articulated Arm is used as an accessory to the ANT-X System. It functions to hold or position the ANT-X Device over the patient's body to allow for needle positioning and alignment during the surgical procedure. The base of the articulated arm is mounted onto the operating bed while the head component is attached to the ANT-X Device. The joints of the articulated arm can be maneuvered to any desired position and comes with a mechanical central locking mechanism, a knob, which can be tightened to lock the arm in place. The FISSO Articulated Arm is delivered non-sterile and must be cleaned, disinfected and sterilized before each use as per manufacturer's Instructions for Use.

The FISSO Articulated Arm device is exempt from Premarket Submission.

## 6. Indications for Use

The ANT-X System is indicated for use in conjunction with fluoroscopy imaging in percutaneous nephrolithotomy (PCNL) procedures to aid in needle positioning and alignment process.

## 7. Substantial Equivalence Discussion:

The ANT-X System is designed to assist interventional radiologists and clinicians in the manual advancement of interventional trocar needles, during fluoroscopic image guided percutaneous nephrolithotomy (PCNL). The ANT-X has the same intended use as its predicate device NuVasive LessRay with Enhanced Tracking, and the reference device iSYS 1. The devices are designed to assist interventional radiologists and clinicians in the positioning of instruments, such as needles in the case of the ANT-X System, for percutaneous procedures that are fluoroscopy-guided. All the three devices require the physician to execute the final gesture, that is, to advance the needle by physically pushing the instrument into the patient.

The ANT-X System is indicated for use in conjunction with fluoroscopy imaging in percutaneous nephrolithotomy (PCNL) procedures to aid in needle positioning and alignment process, while the NuVasive LessRay with Enhanced Tracking is intended for use in any application where a fluoroscope is incorporated. The indications of the ANT-X are the same as the indications of the predicate device, in that fluoroscopy-guided PCNL procedures are a subset of any fluoroscopy-guided treatment applications in which the predicate device is intended for use.

The ANT-X System subject of this submission, the predicate device NuVasive LessRay with Enhanced Tracking, and the reference device iSYS 1 are all powered, computer controlled devices that provide the position of the instrument for the procedure in real time.

The ANT-X System subject of this submission and the NuVasive LessRay with Enhanced Tracking predicate device not only use the image acquired from interventional fluoroscopic X-ray system (2D X-Ray video input), as the intraoperative guidance, but they are both passive devices to the fluoroscope and they do not perform instrument advancement into the patient, which is left as manual task to the clinician.

The ANT-X System differs from the predicate NuVasive LessRay with Enhanced Tracking in the locations of marker placement that is on the robotic system in the ANT-X, as opposed to the markers placed on the fluoroscope and the tracking clip in the predicate device. Moreover, the type of markers used as reference points during image registration represent another difference between the ANT-X System and the predicate device. The ANT-X System uses fiducial markers which differ from the optical gray markers in the NuVasive LessRay with Enhanced Tracking device. Instead, the ANT-X System and the reference device iSYS 1 both use fiducial markers as reference points, their software duplicates 2D fluoroscopy images onto the software UI to provide navigational assistance and monitoring of device deployment during procedure without performing tracking.

Although there are other minor differences in technological characteristics between the ANT-X System and the predicate device, such as the instrumentation, the instrument fixation method, the calibration, the immobilization of the system between patient and device and whether the instrument positioning is done automatically or manually, these minor differences do not raise any additional safety and effectiveness concerns. As the reference device, the ANT-X System serves as a mechanical guide to ensure desired end-effector (needle) trajectory is fixed during puncture. Furthermore, performance tests were conducted on ANT-X to ensure that it is safe and effective for its intended use.

Table 5-1 below compares the intended uses, the indications for use and the technological characteristics of the ANT-X System with the predicate and reference devices.

Differences in technological characteristics between the ANT-X System and the NuVasive LessRay with Enhanced Tracking were evaluated through performance and safety tests (bench studies and animal studies). A feasibility clinical trial was conducted as a reference study for the use of ANT-X System. No new questions of safety and effectiveness was raised, and therefore, it can be concluded that the ANT-X System is substantially equivalent to the selected predicate NuVasive LessRay with Enhanced Tracking device.

**Table 5-1: Side by Side Comparison Table of ANT-X System with Nuvasive LessRay with Enhanced Tracking and iSYS 1**

| Characteristic | Automated Needle Targeting<br><br>(ANT-X) | Predicate<br><br>Nuvasive LessRay with Enhanced Tracking<br><br>K170800 | Reference Device<br><br>iSYS 1<br><br>K131433 | Comparison |
|---|---|---|---|---|
| **510(k) number** | K230185 | K170800 | K131433 | |
| **Primary Product Code** | OWB | OWB | JAK | |
| **Manufacturer** | NDR Medical Technology Pte. Ltd. | NuVasive, Incorporated | ISYS Medizintechnik GmbH | |
| **General Description** | Computer controlled automatic needle alignment robot used during fluoroscopy guided percutaneous procedures. | Software based device used to provide computer display systems interfaced to fluoroscope through a video cable. | Computer controlled electromechanical multi-joined arm indicated for CT and fluoroscopy guided invasive procedures. | |
| **Intended Use** | The ANT-X System assists interventional radiologists and clinicians in the manual advancement of trocar needles during image guided (C-arm fluoroscopy) percutaneous procedures (PCNL). It is a low-risk medical device that helps to create a keyhole access accurately by carrying out automated specific needle targeting while using image guiding with fluoroscopy system. Its primary aim is to carry out accurate needle positioning. | Intended for use with a standard C-arm or fluoroscope during a surgical or interventional procedure. When used in connection with the low dose and/or pulse setting on the fluoroscope, the user may improve the quality (clarity, contrast, noise level and usability) of a noisy (low-quality) image. LessRay with | The intended use of the iSYS1 device is to function as a remote- operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/ angulation is done based on 2D/3D patient data (CT, cone- beam CT, fluoroscopy) by external planning software – for example using an external navigation system or planning software coming | Same Intended Use as the predicate and reference devices, in the sense that the devices are intended to use C-arm fluoroscopic images to aid the clinician in positioning the instrumentation for percutaneous procedures. |

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| | | Enhanced Tracking has additional capability of instrument tracking to aid the user in positioning an instrument using prior baseline x-rays. | with the used imaging device. Also, verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1- System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like. | |
| **Indication for Use** | The ANT-X System is indicated for use in conjunction with fluoroscopy imaging in percutaneous nephrolithotomy (PCNL) procedures to aid in needle positioning and alignment process. | Indicated for use in any application where a fluoroscope is incorporated to aid in diagnosis and treatment of disease. | The iSYS 1 device is a user controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device. Applications include, but are not limited to, interventions like | Same Indications for use as the predicate device, as the PCNL procedures where the ANT-X is intended for use are a subset of any fluoroscopic guided procedure in which the predicate device is intended to be used. |

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| | | | biopsy procedures, tumor ablation, nerve blocking, electrode placement, etc | |
| **Intended User(s)** | Trained physicians | Trained physicians | Trained physicians | Same to the predicate and reference devices |
| **Used with imaging Guidance** | Yes | Yes | Yes | Same to the predicate and reference devices. |
| **Powered** | Yes | Yes | Yes | Same. |
| **Computer controlled** | Yes | Yes | Yes | Same |
| **Real-time Instrument Position** | Yes | Yes | Yes | Same. |
| **Imaging Modality** | Fluoroscopy | Fluoroscopy | Fluoroscopy and computed tomography | Same to the predicate and reference devices. |
| **Video Input Image** | 2D X-ray | 2D X-ray | N.A. iSYS 1 uses an external third-party software that is not part of the system. | Same to the predicate device. Different to the reference device. |
| **Localization means** | Fiducial markers on robotic device | Optic markers on the tracking clip fitted on the instrument and the fluoroscope. | Fiducial markers on tool holder | Different Locations of Markers placement from both the predicate and the reference device. |
| **Registration Method** | Fiducial Markers | Optical Markers | Fiducial Markers | Same to the reference device, as the same type of marker (fiducial) are used.. Different from the predicate device. |

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| **Planning and navigation software** | Directly duplicates 2D fluoroscopy images onto software UI to provide navigational assistance and monitoring of device deployment during procedure. | N.A. Nuvasive LessRay uses an off-the-shelf tracking system to guide the user in positioning the instrument | N.A. iSYS 1 uses an external third-party software for planning and monitoring of device deployment during procedure. | Different to both predicate and reference device. |
| **Instrumentation** | ANT-X Device<br><br>ANT-X Needle Holder<br><br>ANT-X Software<br><br>ANT-X Controller Box<br><br>FISSO Instrument Holder<br><br>(Model 3840.40) | Computer Screen Camera Table arrays C-arm collar arrays C-arm collar Tracking Snaps | Robotic Positioning Unit<br><br>Instrument Guide<br><br>Control Unit<br><br>Handheld Control Unit<br><br>Table Adapter<br><br>Gross Positioning Arm | Different instrumentation to both the predicate and reference devices. |
| **Instrument Fixation** | Robot is mounted to operating table using a FISSO Instrument Holder, Model 3840.40 (US FDA Class I Exempt). It does not have direct contact with the patient's body | C-arm collar arrays and table arrays are used in order to mount the off-the-shelf tracking hardware to the C-arm and to the operating table. It does not have direct contact with the patient's body. | Robot is mounted to operating table using a gross positioning arm and table adapter. It does not have direct contact with the patient's body | Different mounting instruments to both predicate and reference device. |
| **System immobilization between patient and** | Yes | No | Yes | Same to the reference device. Different from the predicate device. |

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| **device** | | | | |
| **Instrument Calibration** | Intraoperative | Not required | Intraoperative | Same to the reference device. Different from the predicate device. |
| **Device end effector trajectory alignment** | Auto alignment to desired trajectory | Manual alignment to desired trajectory via manual freehand technique | Manual alignment to desired trajectory using handheld control unit | Different to both predicate and reference device. |
| **Execution of final gesture after trajectory alignment** | Physician executes final gesture via manual advancement of device end effector | Physician executes final gesture via manual advancement of the instrument | Physician executes final gesture via manual advancement of device end effector | Same to both predicate and reference device. |
| **Mechanical Guidance For Device End-effector** | Yes, the device serves as a mechanical guide to ensure desired needle (end-effector) trajectory is fixed during puncture. | No, the instrument is manipulated via manual freehand technique | Yes, the device serves as a mechanical guide to ensure desired needle (end-effector) trajectory is fixed during puncture. | Same mechanical guidance principle as the reference device. Different from the predicate device. |
| **Image Registration Error** | 0.01- 0.45mm | Unknown | 0.38 ± 0.18 mm | Similar. The ANT-X image registration error (mean) is comparable to the reference device's error. |
| **Alignment Accuracy Range (Target error)** | 0.14-0.97mm | Unknown | 0.1-4mm | Similar. The subject device alignment accuracy range is within the range of the reference device's target error. |
| **Sterility Assurance Level** | SAL $10^{-6}$ | Unknown | SAL $10^{-6}$ | Same as the reference device. |
| **Biocompatibility** | -Cytotoxicity<br>-Sensitization<br>-Irritation<br>-Material-mediated<br>-Pyrogenicity<br>-Acute systemic toxicity | NA- no patient contacting components | NA- no patient contacting components | Different to both predicate and reference device, due to the presence of an indirect patient contacting component (Needle Holder) in the subject device. |

## 8. Performance Data

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

**Biocompatibility**
Biocompatibility tests in accordance with Annex A of ISO 10993-1:2018 was conducted to evaluate the potential biological risks arising from the use of the ANT-X Needle Holder. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Material-mediated pyrogenicity
- Acute systemic toxicity

The ANT-X Needle Holder is considered an externally communicating medical device which has indirect contact with the internal body tissues. The duration of contact, when used as intended, is ≤ 24 h. The ANT-X Needle Holder has been validated to be biologically safe for use in a surgical setting and is considered to be biocompatible.

**Sterilization**
The only component of the ANT-X System that is supplied sterile is the ANT-X Needle Holder, which is intended to be attached to the ANT-X Device during use. ANT-X Needle Holders are for single-use only and are sterilized using Ethylene Oxide sterilization. The sterilization method has been validated in accordance with ISO 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices to demonstrate a Sterility Assurance Level (SAL) of $10^{-6}$. The ETO and ECH sterilant residual levels are also found to be within acceptable levels.

**Shelf Life**
Real time studies were conducted to validate a one-year shelf life of the ANT-X Needle Holder. Sterility and packaging validation testing and functional testing demonstrated that the ANT-X Needle Holder sterility and quality are maintained at 1 year of real time storage conditions.

**Electrical Safety and Electromagnetic Compatibility (EMC)**
Electrical safety and EMC testing were conducted on ANT-X System consisting of the controller box, device, software and third-party instrument holder. The system complies with the IEC 60601-1 standard for Safety and the IEC 60601-1-2 for EMC.

**Software Verification and Validation Testing**
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this

subject device was considered as a “moderate” level of concern.

**Bench Testing**

Software Tracking Accuracy including marker detection

The purpose of this testing was to verify that the ANT-X System software is able to provide accurate tracking of individual points in plane under C-arm fluoroscopy imaging. The test results showed that the tracking accuracy of ANT-X Software meet the design acceptance criteria.

Positional Repeatability

The purpose of this testing was to verify that the robot can achieve positional repeatability when instructed to move to specific locations from the home position repeatedly over multiple trials. The test demonstrated that the system met specifications and the repeatability accuracy is within the acceptable limit.

Bullseye Alignment Accuracy

The purpose of this testing was to verify that the ANT-X System is able to provide an accurate bullseye alignment between two points selected by the user under C-arm fluoroscopy. The testing demonstrated that ANT-X System met specifications.

Puncture Accuracy

The purpose of this testing was to verify that the ANT-X System can ultimately achieve a successful puncture of a specific target size. The test demonstrated that the ANT-X System met its specifications.

**Animal Study**

Pre-clinical animal testing was conducted on the ANT-X System to demonstrate the functionality and performance of the device. Percutaneous access to the target site, the kidneys (PAK), using the ANT-X System are compared to the conventional free-hand, unassisted procedure performed by fellowship-trained surgeons. Animal trials were successful and the performance of the ANT-X System were satisfactory. The performance of ANT-X System is concluded to be consistent and that it can be used in fluoroscopy guided procedure safely.

**Clinical Study**

A feasibility clinical study was conducted as a reference study for the safe use of the ANT-X System in PCNL procedures.

A randomized, single-blind clinical trial comparing the surgical outcomes of Robotic Assisted Fluoroscopy (RAF)- and Ultrasound (US)-guided renal access in mini-PCNL was conducted in Japan. The intention of the study was to prove the non-inferiority of ANT-X over US-guided Endoscopic combined intrarenal surgery (ECIRS), one of the most ideal methods currently utilized for PCNL. A total of 71 patients were randomized for the study, 35 in the USG group and 36 in the RAFG group. No significant differences were observed between the two groups in terms of other preoperative factors, including patient background, hydronephrosis and stone characteristics.

Primary objective:
Stone-free rate (SFR) at 3 months after surgery. SFR is defined as following: no residual fragments larger than 4 mm detected in kidney ureter bladder (KUB) radiography at 1 month after surgery and no residual fragments larger than 2 mm detected by computed tomography (CT) 3 months after surgery.

Secondary objectives:

- Overall complication rate and Clavien-Dindo classification complication rates.
- Renal puncture time
- Total operation time
- Number of successful punctures
- Fluoroscopy time

Efficacy evaluation
The SFR at 3 months after surgery in the US and RAF groups was 70.6% and 83.3 %, respectively (p=0.26). Overall, the results were comparable for both ANT-X and ultrasound-guided access procedures.

The RAFG and US groups showed similar trends in the selection of renal calyces for percutaneous access. In the US group, 14.3% of patients had a puncture surgeon change, whereas puncture surgeon change during percutaneous renal access was not required in the RAF group (p=0.025). The mean number of needle punctures was significantly fewer in the RAF group than that in the USG group (1.83 times vs. 2.51 times, p=0.025). The median needle puncture duration was also significantly shorter in the RAF group than in the USG group (5.5 minutes vs. 8.0 minutes, p=0.049). Moreover, there were no statistical differences in other intraoperative parameters, such as percutaneous tract size, tubeless cases, and device set/ percutaneous access/ fragmentation/ surgery/ fluoroscopy durations. The ANT-X System resulted to be as easy to use as the ultrasound-guided PCNLs to resident doctors still in training and demonstrated to require less puncture surgeon changes, fewer punctures attempts and reduced puncturing time.

Safety evaluation
The study demonstrated that the robotic assisted fluoroscopy-guided PCNL procedure is as safe as the control ultrasound-guided PCNL, as no significant differences were observed between the RAFG and USG groups in overall complication rates, complications within the first month after the surgery, or between the complications within 1 and 3 months. The results of the regression analysis demonstrates that the complications in the study are not related to or caused by the use of the ANT-X device, as they are directly associated with the dilation of the renal tract after needle insertion is performed by the surgeon after the ANT-X System is used and removed from the operating area.

It is noted that the overall complication rates between the robotic-assisted fluoroscopic-guided procedures and ultrasound-guided procedures presented in this study are not statistically significant (p-value = 0.396) and also the rates of complications within one month are not statistically significant (p=0.88). Even if this study showed only that the use of the ANT-X device did not have effect on the adverse events for the entire PCNL procedure as opposed to

use of the ANT-X system alone, it allowed to answer the basic question of the relationship between the occurring complications and the use of the ANT-X System, and to exclude that complications arise from the use of the ANT-X System. These results support the safety of the ANT-X System as adjunctive method to perform safe fluoroscopy-guided PCNL procedures.

Summary

The results of the study indicated that ANT-X is a feasible, safe, and comparable as the control ultrasound-guided PCNL method of percutaneous nephrolithotomy (PCNL) for kidney stone procedure. Its safety and efficacy evaluations are comparable to the control.

**9. Conclusion:**

Based on the information provided in this 510(k) premarket notification, NDR Medical Technology Pte Ltd. concludes that the ANT-X is substantially equivalent to the Nuvasive LessRay with Enhanced Tracking predicate device.