



October 22, 2021

NeoTract, Inc.
Brian Gall
Senior Manager of Regulatory Affairs
4155 Hopyard Road
Pleasanton, California 94588

Re: K212396

Trade/Device Name: UroLift System Rigid Retrieval Kit Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: September 22, 2021
Received: September 23, 2021

Dear Brian Gall:

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,

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K212396

Device Name
UroLift® System Rigid Retrieval Kit Sterilization Tray

Indications for Use (Describe)

The UroLift System Rigid Retrieval Kit Sterilization Tray is intended to be used to enclose and protect surgical instruments optionally used for the UroLift System procedure for storage and sterilization in a prevacuum steam sterilizer.

The following instruments are intended to be loaded into the UroLift System Rigid Retrieval Kit Sterilization Tray:

- UL-SCOPE4-0 / UL-SCOPE4-0-FE* – Cystoscope, 4.0 mm diameter x 302 mm length, 0° angle of view, wide angle
- UL-GRASP-R – Optical Graspers, double action jaws
- UL-SCI-R – Optical Scissors, double action jaws

* Factory Exchange: Devices with a part number ending in “FE” have been repaired to meet product specifications.

The tray by itself is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, 510(k) cleared sterilization wrap to maintain sterility of the enclosed instruments when sterilized using the following prevacuum steam sterilization cycles:

Prevacuum Steam

Temperature: 132°C (270°F)

Sterilization time: 4 minutes

Minimum dry time: 30 minutes

Maximum weight: 5 lbs (2.7 kg)

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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510(k) SUMMARY K212396

COMPANY INFORMATION

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Pleasanton, CA 94588
Registration Number: 3015181082

SUBMISSION CORRESPONDENT

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DATE PREPARED

20 October 2021

DEVICE INFORMATION

Trade Name: UroLift® System Rigid Retrieval Kit Sterilization Tray (UL-RRKTRAY)
Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Classification Name: Sterilization Wrap
Product Code: KCT
Regulation Number: 880.6850
Classification: II
Classification Panel: Surgical and Infection Control Devices (OHT4)
Infection Control and Plastic and Reconstructive Surgery (DHT4B)

DEVICE DESCRIPTION

The UroLift System Rigid Retrieval Kit Sterilization Tray is a rigid containment device consisting of a base with lid which enables reprocessing of surgical instruments that are optionally used in the UroLift System Procedure.

INDICATIONS FOR USE

The UroLift System Rigid Retrieval Kit Sterilization Tray is intended to be used to enclose and protect surgical instruments optionally used for the UroLift System procedure for storage and sterilization in a pre-vacuum steam sterilizer. The following instruments are intended to be loaded into the UroLift System Rigid Retrieval Kit Sterilization Tray:

- **UL-SCOPE4-0 / UL-SCOPE4-0-FE** – Cystoscope, 4.0 mm diameter x 302 mm length, 0° angle of view, wide angle
- **UL-GRASP-R** – Optical Graspers, double action jaws

- **UL-SCI-R** – Optical Scissors, double action jaws

* Factory Exchange: Devices with a part number ending in “FE” have been repaired to meet product specifications.

The tray by itself is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, 510(k) cleared sterilization wrap to maintain sterility of the enclosed instruments when sterilized using the following pre-vacuum steam sterilization cycles:

Pre-Vacuum Steam	
Temperature	132°C (270°F)
Sterilization Time	4 minutes
Minimum Dry Time	30 minutes
Maximum Weight	2.27 kg / 5.0 lbs

CONTRAINDICATIONS

There are no known contraindications.

PREDICATE DEVICE

The predicate device is the UroLift System Procedure Kit Sterilization Tray, NeoTract / Teleflex (K192781).

Trade Name: UroLift System Procedure Kit Sterilization Tray (UL-PKTRAY)

Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

Product Code: KCT

Regulation Number: 880.6850

Classification: II

Classification Panel: Surgical and Infection Control Devices (OHT4)



Infection Control and Plastic and Reconstructive Surgery (DHT4B)

COMPARISON WITH THE PREDICATE DEVICE

The legally-marketed UroLift System Procedure Kit Sterilization Tray cleared via K192781 (14 April 2020) is the predicate for the UroLift System Rigid Retrieval Kit Sterilization Tray since both are metal sterilization trays with similar indications for use. Also, the predicate device and the proposed sterilization tray can undergo pre-vacuum steam sterilization with similar cycles. The primary differences are the size of the tray and the validated dry time. The differences do not affect the safety and effectiveness of the device as demonstrated through the cleaning and sterilization validation.

Technological Comparison Table:

Characteristic	Subject Device UroLift® System Rigid Retrieval Kit Sterilization Tray [K212396]	Predicate Device UroLift System Procedure Kit Sterilization Tray [K192781]	Comparison
Device Name	UroLift® System Rigid Retrieval Kit Sterilization Tray	UroLift System Procedure Kit Sterilization Tray	N/A
510(k) Number	K212396	K192781	N/A

Product Code	KCT	KCT	Same															
Product Class	Class II	Class II	Same															
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same															
Indications for Use	<p>The UroLift System Rigid Retrieval Kit Sterilization Tray is intended to be used to enclose and protect surgical instruments optionally used for the UroLift System procedure for storage and sterilization in a prevacuum steam sterilizer. The following instruments are intended to be loaded into the UroLift System Rigid Retrieval Kit Sterilization Tray:</p> <ul style="list-style-type: none"> • UL-SCOPE4-0 / UL-SCOPE4-0-FE* – Cystoscope, 4.0 mm diameter x 302 mm length, 0° angle of view, wide angle • UL-GRASP-R – Optical Graspers, double action jaws • UL-SCI-R – Optical Scissors, double action jaws <p>* Factory Exchange: Devices with a part number ending in “FE” have been repaired to meet product specifications.</p> <p>The tray by itself is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, 510(k) cleared sterilization wrap to maintain sterility of the enclosed instruments when sterilized using the following pre-vacuum steam sterilization cycles:</p> <p>Pre-vacuum Steam Temperature: 132°C (270°F) Sterilization time: 4 minutes Minimum dry time: 30 minutes Maximum weight: 5 lbs (2.7 kg)</p>	<p>The UroLift System Procedure Kit Sterilization Tray is intended to be used to enclose and protect surgical instruments used for the UroLift System Procedure for storage and sterilization in a pre-vacuum steam sterilizer.</p> <p>The following instruments are intended to be loaded into the UroLift System Procedure Kit Sterilization Tray:</p> <p>UL-SCOPE / UL-SCOPE-FE – Cystoscope, 2.9 mm diameter x 365 mm length, 0° angle of view, 85° field of view</p> <p>UL-SHEATH / UL-SHEATH-FE – Sheath, 20 Fr., with 2 tube connectors (Luer lock and Luer lock with stopcock)</p> <p>UL-VO / UL-VO-FE – Visual obturator, 20 Fr.</p> <p>The tray by itself is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, 510(k) cleared sterilization wrap to maintain sterility of the enclosed instruments when sterilized using the following pre-vacuum steam sterilization cycles:</p> <table border="1"> <thead> <tr> <th colspan="3">Pre-Vacuum Steam</th> </tr> </thead> <tbody> <tr> <td>Temperature</td> <td>132°C (270°F)</td> <td>134°C (273°F)</td> </tr> <tr> <td>Sterilization Time</td> <td>4 minutes</td> <td>3 minutes</td> </tr> <tr> <td>Minimum Dry Time</td> <td>30 minutes</td> <td>20 minutes</td> </tr> <tr> <td>Maximum Weight</td> <td colspan="2">1.8 kg / 4.0 lbs</td> </tr> </tbody> </table>	Pre-Vacuum Steam			Temperature	132°C (270°F)	134°C (273°F)	Sterilization Time	4 minutes	3 minutes	Minimum Dry Time	30 minutes	20 minutes	Maximum Weight	1.8 kg / 4.0 lbs		Different
Pre-Vacuum Steam																		
Temperature	132°C (270°F)	134°C (273°F)																
Sterilization Time	4 minutes	3 minutes																
Minimum Dry Time	30 minutes	20 minutes																
Maximum Weight	1.8 kg / 4.0 lbs																	
Reusability	Reusable	Reusable	Same															
Patient Contact	No direct patient contact	No direct patient contact	Same															
Design	Rigid containment device consisting of a base with lid which can be fastened by a latching mechanism. The device is perforated in order to enable reprocessing of enclosed medical devices held in place by silicone retainers.	Rigid containment device consisting of a base with lid which can be fastened by a latching mechanism. The device is perforated in order to enable reprocessing of enclosed medical devices held in place by silicone retainers.	Same															
Device Image			Similar															

Materials of Construction	Stainless steel, silicone, Radel	Stainless steel, silicone, Radel	Same
Dimensions	5.3 (W) x 20.7 (L) x 1.75 (H) inches	4.5 (W) x 20 (L) x 2.125 (H) inches	Similar
Air Permeance	Yes	Yes	Same
Material Biocompatibility	Materials are biocompatible. Tested per ISO 10993-1 and Use of International Standard ISO 10993-1, "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 16 June 2016	Materials are biocompatible. Tested per ISO 10993-1 and <i>Use of International Standard ISO 10993-1, "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 16 June 2016</i>	Same
Sterilization Method	Pre-vacuum Steam Sterilization	Pre-vacuum Steam Sterilization	Same
Sterilization Parameters	132 °C Pre-vacuum Steam Cycle Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Vacuum dry time: 30 minutes	132 °C Pre-vacuum Steam Cycle Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Vacuum dry time: 30 minutes 134 °C Pre-vacuum Steam Cycle Exposure temperature: 273 °F (134 °C) Exposure time: 3 minutes Vacuum dry time: 20 minutes	Similar

SUMMARY OF NON-CLINICAL TESTING

Title of test	Purpose of test	Acceptance Criteria / Source of references	Results
Usability Testing	Usability testing assured that the user could perform the steps of the Instructions for Use to meet the intended use of the sterilization tray and assured that the sterilization tray performed as intended to securely store and sterilize the instruments	The user is able to load and unload the tray, perform the reprocessing workflow (Clean the tray, inspect the tray, clean and inspect the instruments, and load the tray and sterilize), and determine the end of the serviceable life of the tray. <i>ANSI/AAMI ST77:2013 – Containment devices for reusable medical device sterilization</i>	Pass
Cytotoxicity Testing	The purpose of this study is to evaluate the cytotoxicity of a test article extract using an in vitro mammalian cell culture test.	The test sample meets the requirements of the test if the biological response is less than or equal to grade 2 (mild). <i>Cytotoxicity testing per ISO 10993-5:2009 – Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity</i>	Pass
Sensitization Testing	The purpose of this study is to evaluate the potential of the test	Grades of 1 or greater observed in the test group generally indicate	Pass

	article to cause delayed dermal contact sensitization in the guinea pig maximization test.	sensitization, provided that grades of less than 1 are observed on the control animals. If grades of 1 or greater are noted on control animals, then the reactions of test animals that exceeded the most severe control reaction will be considered to be due to sensitization. Sensitization testing per <i>ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization</i>	
Intracutaneous Reactivity Testing	The purpose of this study is to evaluate the local dermal irritation of a test article extract following intracutaneous injection in rabbits.	The difference of overall mean of the test group to the control group on erythema and edema score must be less than 1. Intracutaneous Reactivity testing per <i>ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization</i>	Pass
Useful Life Testing	The tray was subject to 100 cleaning and sterilization cycles per the Instructions for Use reprocessing directions. The purpose of the test was to determine the serviceable life span of the tray.	The tray must pass the inspection criteria on the IFU after 100 reprocessing cycles. <i>ANSI/AAMI ST77:2013 – Containment devices for reusable medical device sterilization</i>	Pass
Cleaning Validation	The purpose of this test is to validate that the cleaning instructions listed in the Instructions for Use appropriately clean the tray to ensure the sterilization cycle will be effective.	Per the protocol, there were three acceptance criteria; protein residual analysis, hemoglobin residual analysis, and visual inspection. The protein residual benchmark level was 6.4µg/cm ² and the hemoglobin benchmark level was 2.2µg/cm ² . The tray must pass the visual inspection in the IFU. <i>AAMI TIR30: 2011/(R)2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices revised 15 December 2016 and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug</i>	Pass

		Administration Staff issued 17 March 2015	
Sterilization Validation	The purpose of this test is to validate that the sterilization instructions listed in the Instructions for use appropriately sterilize the tray and contents.	The minimum sterility assurance level (SAL) of 10 ⁻⁶ can be achieved if the sterilization instructions in the IFU were followed. <i>ANSI/AAMI ST77:2013, Containment devices for reusable medical device sterilization</i>	Pass

PERFORMANCE TESTING

The design requirements for the UroLift System Rigid Retrieval Kit Sterilization Tray were reviewed and non-clinical design verification testing was required to assure that the device met the intended use. Non-clinical testing included usability testing, and cleaning / sterilization testing. The usability testing assured that the user could perform the steps of the Instructions for Use to meet the intended use of the sterilization tray and assured that the sterilization tray performed as intended to securely store and sterilize the instruments.

BIOCOMPATIBILITY TESTING

The biocompatibility of the UroLift System Rigid Retrieval Kit Sterilization tray is equivalent to the predicate. Both trays are manufactured using identical materials and equivalent processing methods. The type and duration of contact of the proposed and predicate tray are identical, and the instruments contained in both trays are identical duration and contact type. As such, the biocompatibility of the predicate is considered representative of the proposed tray and no additional biocompatibility testing was required.

The predicate device (UroLift System Procedure Kit Sterilization Tray) has been tested for biocompatibility and passed the relevant tests according to ISO 10993-1: *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and *Use of International Standard ISO 10993-1, "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 September 2020. Biocompatibility testing was performed on worst case sterilized devices and included:

- Cytotoxicity testing per *ISO 10993- 5:2009 – Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*
- Sensitization testing per *ISO 10993- 10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization*
- Intracutaneous Reactivity testing per *ISO 10993- 10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization*

CLEANING / STERILIZATION TESTING

The UroLift System Rigid Retrieval Kit Sterilization Tray is intended to be sold non-sterile and used during the reprocessing of the surgical instruments that are optionally used in the UroLift System Procedure. As such, cleaning and sterilization validations were performed to ensure the tray could withstand multiple reprocessing cycles without adverse reaction or

degradation.

The cleaning validation was designed to simulate the worst case scenario conforming to several industry standards including *AAMI TIR30: 2011/(R)2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices* revised 15 December 2016 and *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* issued 17 March 2015. The cleanliness of the tray was assessed by protein and hemoglobin residuals, and all residuals met predefined acceptance criteria demonstrating the adequate cleanliness of the tray using the cleaning instructions.

The sterilization validation, designed based on the FDA-recognized standard *ANSI/AAMI ST77:2013, Containment devices for reusable medical device sterilization*, demonstrated the minimum sterility assurance level (SAL) of 10^{-6} can be achieved if the sterilization instructions in the instructions for use (IFU) were followed.

The reuse life of the UroLift System Rigid Retrieval Kit Sterilization tray is equivalent to the predicate. Both trays are manufactured using identical materials and equivalent processing methods, and subject to equivalent cleaning and sterilization cycles. As such, the reuse life of the predicate (100 cycles) is considered adequate for the proposed tray and no additional reuse life testing was required. Inspection criteria are the same as the predicate and described in the instructions for use (IFU).

CONCLUSION

The conclusions drawn from the non-clinical tests demonstrate the UroLift System Rigid Retrieval Kit Sterilization Tray is as safe, as effective, and performs as well as or better than the legally marketed predicate device.