April 14, 2020

NeoTract, Inc.
Brian Gall
Regulatory Affairs Manager
4155 Hopyard Rd.
Pleasanton, California 94588

Re: K192781
Trade/Device Name: UroLift® System Procedure Kit Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 11, 2020
Received: March 13, 2020

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 Christopher K. Dugard, M.S.
Acting 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

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)*
K192781

Device Name
UroLift® System Procedure Kit Sterilization Tray

Indications for Use *(Describe)*
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.

The following instruments are intended to be loaded into the UroLift System Procedure Kit Sterilization Tray:
- UL-SCOPE / UL-SCOPE-FE – Cystoscope, 2.9 mm diameter x 365 mm length, 0° angle of view, 85° field of view
- UL-SHEATH / UL-SHEATH-FE – Sheath, 20 Fr., with 2 tube connectors (Luer lock and Luer lock with stopcock)
- UL-VO / UL-VO-FE – Visual obturator, 20 Fr.

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:

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

The maximum weight of the tray is 1.8kg / 4lbs.

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

COMPANY INFORMATION

NeoTract, Inc.
4155 Hopyard Road
Pleasanton, CA 94588
Registration Number: 3015181082

SUBMISSION CORRESPONDENT

Brian Gall
Regulatory Affairs Manager, Interventional Urology
NeoTract, Inc.
4155 Hopyard Road
Pleasanton, CA 94588

Telephone – 925.329.6547
E-mail – brian.gall@teleflex.com

DATE PREPARED

13 April 2020

DEVICE INFORMATION

Trade Name: UroLift® System Procedure Kit Sterilization Tray (UL-PKTRAY)
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 Procedure Kit Sterilization Tray is a rigid containment device consisting of a base with lid which enables reprocessing of the surgical instruments used in the UroLift System Procedure.

INTENDED USE

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

- **UL-SCOPE / UL-SCOPE-FE** – Cystoscope, 2.9 mm diameter x 365 mm length, 0° angle of view, 85° field of view
- **UL-SHEATH / UL-SHEATH-FE** – Sheath, 20 Fr., with 2 tube connectors (Luer lock and Luer lock with stopcock)

- **UL-VO / UL-VO-FE** – Visual obturator, 20 Fr.

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)	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	

CONTRAINDICATIONS

There are no known contraindications.

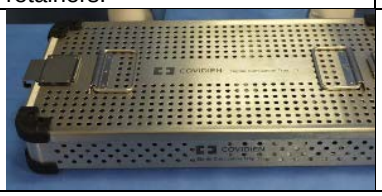
PREDICATE DEVICE

The predicate device is the Signia™ Sterilization Tray from Medtronic® (formerly Covidien®) (K161347).

Trade Name: Signia Sterilization Tray
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)

Technological Comparison Table:

Characteristic	**Predicate Device** Signia™ Sterilization Tray K161347	**Subject Device** UroLift System Procedure Kit Sterilization Tray [K192781]	**Comparison**
Device Name	Signia™ Sterilization Tray	UroLift System Procedure Kit Sterilization Tray	N/A
510(k) Number	K161347	TBD	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**

<table>
<tr><td>Indications for Use</td><td>The Signia™ sterilization tray is intended to provide storage for the Signia™ adapters, Signia™ reusable insertion guide and Signia™ manual retraction tool during sterilization, storage and transportation within the hospital environment. The Signia™ sterilization tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non- stacked configuration. The tray can contain at a maximum:</td><td>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.
The following instruments are intended to be loaded into the UroLift System Procedure Kit Sterilization Tray:
• UL-SCOPE / UL-SCOPE-FE – Cystoscope, 2.9 mm diameter x 365 mm length, 0° angle of view, 85° field of view
• UL-SHEATH / UL-SHEATH-FE – Sheath, 20 Fr., with 2 tube connectors</td><td>Similar</td></tr>
<tr><td></td><td>one (1) Signia™ adapter, one (1) Signia™ reusable insertion guide and one (1) Signia™ manual retraction tool. The tray is intended to allow steam sterilization of the enclosed medical devices. The validated sterilization cycle parameters are as follows:
STEAM STERILIZATION
Pre-vacuum (HiVac) Steam Cycles
<table>
<tr><td>Item: Tray with components wrapped or in sterilization container system</td><td>132 °C Pre-vacuum (HiVac) Steam Cycles</td></tr>
<tr><td>Exposure temperature</td><td>270 °F (132 °C)</td></tr>
<tr><td>Exposure time</td><td>4 minutes</td></tr>
<tr><td>Vacuum dry time</td><td>20 - 40 minutes</td></tr>
</table></td><td>(Luer lock and Luer lock with stopcock)
• UL-VO / UL-VO-FE – Visual obturator, 20 Fr.
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:
<table>
<tr><th colspan="3">Pre-Vacuum Steam</th></tr>
<tr><th></th><th>Value for the United States</th><th>Value for Other Countries</th></tr>
<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>
</table></td><td></td></tr>
<tr><td>Reusability</td><td>Reusable</td><td>Reusable</td><td>Same</td></tr>
<tr><td>Patient Contact</td><td>No direct patient contact</td><td>No direct patient contact</td><td>Same</td></tr>
<tr><td>Design</td><td>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.</td><td>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.</td><td>Same</td></tr>
<tr><td>Device Image</td><td>  </td><td> 
</td><td>N/A</td></tr>
</table>

Materials of Construction	Stainless steel, silicone	Stainless steel, silicone, Radel	Same

Dimensions	10.0 (W) x 21.4 (L) x 3.0 (H) inches	4.5 (W) x 20 (L) x 2.125 (H) inches	**Similar**
Air Permeance	Yes	Yes	**Same**
Material Biocompatibility	Cytotoxicity	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	**Similar**
Sterilization Method	Pre-vacuum Steam Sterilization	Pre-vacuum Steam Sterilization	**Same**
Sterilization Parameters	**132 °C Pre-vacuum (Hi Vac) Steam Cycle** Exposure temperature: 270 °F (132 °C) Exposure time: 4 minutes Vacuum dry time: 20 - 40 minutes **134 °C Pre-vacuum (Hi Vac) Steam Cycle** Exposure temperature: 273 °F (134 °C)	**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

The design requirements for the UroLift Procedure 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, biocompatibility 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. A summary of the non-clinical testing is below:

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. *ANSI/AAMI ST77:2013 – Containment devices for reusable medical device sterilization*	**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). Cytotoxicity testing per *ISO 10993-5:2009 – Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*	**Pass**
Sensitization Testing	The purpose of this study is to evaluate the potential of the test article to cause delayed dermal contact sensitization in the guinea pig maximization test.	Grades of 1 or greater observed in the test group generally indicate 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 *ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization*	**Pass**
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 *ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization*	**Pass**

Title of test	Purpose of test	Acceptance Criteria / Source of references	Results
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. *ANSI/AAMI ST77:2013 – Containment devices for reusable medical device sterilization*	**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. *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	**Pass**
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. *ANSI/AAMI ST77:2013, Containment devices for reusable medical device sterilization*	**Pass**

BIOCOMPATIBILITY TESTING

The 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 16 June 2016.

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 Procedure Kit Sterilization Tray is intended to be sold non-sterile and used during the reprocessing of the surgical instruments 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 tray was validated to be reused for up to 100 cleaning/sterilization cycles. Careful inspection is the best way to determine the end of serviceable life. Inspection criteria are described in the instructions for use (IFU).

CONCLUSION

The conclusions drawn from the nonclinical tests that demonstrate that the NeoTract UroLift System Procedure Kit Sterilization Tray is as safe, as effective, and performs as well as or better than the legally marketed device.