September 22, 2023

NeoTract, Inc.
% Kelsey Krische
Senior Manager, Regulatory Affairs Product Management
Teleflex Medical, Inc.
3015 Carrington Mill Boulevard
Morrisville, NC 27560

Re: K232558
Trade/Device Name: UroLift 2 ATC Advanced Tissue Control System
Regulation Number: 21 CFR§ 876.5530
Regulation Name: Implantable Transprostatic Tissue Retractor System
Regulatory Class: II
Product Code: PEW
Dated: August 23, 2023
Received: August 23, 2023

Dear Kelsey Krische:

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232558

Device Name
UroLift 2 ATC Advanced Tissue Control System

Indications for Use *(Describe)*
The UroLift System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

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

Kelsey Krische
Senior Manager, Regulatory Affairs, Product Management
Teleflex Medical, Inc.
3015 Carrington Mill Blvd.
Morrisville, NC 27560

Telephone – 303.775.6821
E-mail – IUBU.regulatory@teleflex.com

DATE PREPARED

22 August 2023

DEVICE INFORMATION

Trade Name:	UroLift 2 ATC Advanced Tissue Control System
Common Name:	Implantable Transprostatic Tissue Retractor System
Regulation Name:	Implantable Transprostatic Tissue Retractor System
Product Code:	PEW
Regulation Number:	876.5530
Classification:	II
Classification Panel:	Reproductive, Gastro-Renal, Urological, General Hospital Device and Human Factors (OHT3) Reproductive and Urology Devices (DHT3B)

DEVICE DESCRIPTION

The UroLift 2 ATC Advanced Tissue Control System is a modification of the UroLift 2 System (last cleared in K201837). The primary difference is the addition of a wing component on the distal tip of the UroLift 2 ATC Advanced Tissue Control System which provides a larger footprint. This design feature is intended to provide better mobilization of tissue when performing the UroLift System procedure.

The UroLift System (both the UroLift 2 and UroLift 2 ATC) is designed to access the prostatic urethra and deliver one UroLift Implant through a lobe of the prostate. The UroLift 2 System is inserted into the urethra through the penile orifice and used to displace the urethra toward the prostatic capsule. The UroLift Implant is then deployed transversely through the prostatic tissue. Multiple implants are deployed in the UroLift 2 System procedure. The implants secure the retracted position of the urethra, thereby maintaining an expanded urethral lumen, reducing fluid obstruction and improving lower urinary tract symptoms (LUTS). This is accomplished by holding the approximated position of the inner (urethral) tissue and the outer (capsular) tissue of the prostate with

the UroLift Implant. The procedure typically requires 2-6 implants to retract the obstruction. The UroLift 2 ATC Advanced Tissue Control System consists of two main components, the UL2 Delivery Handle and the UroLift 2 ATC Implant Cartridge (single use). Each UroLift 2 ATC Implant Cartridge comes pre-loaded with one UroLift Implant. The Delivery Handle with the Implant Cartridge installed is known as the Delivery Device.

INTENDED USE

The UroLift 2 ATC Advanced Tissue Control System is indicated for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia, in men 45 years of age or older.

CONTRAINDICATIONS

The UroLift 2 ATC Advanced Tissue Control System should not be used if the patient has:

- Prostate volume of >100 cc
- A urinary tract infection
- Urethra conditions that may prevent insertion of delivery system into bladder
- Urinary incontinence due to incompetent sphincter
- Current gross hematuria

PREDICATE DEVICE

The predicate device is the UroLift 2 System from NeoTract (K201837).

Trade Name:	UroLift 2 System
Common Name:	Implantable Transprostatic Tissue Retractor System
Regulation Name:	Implantable Transprostatic Tissue Retractor System
Product Code:	PEW
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Classification:	II
Classification Panel:	Reproductive, Gastro-Renal, Urological, General Hospital Device and Human Factors (OHT3) Reproductive and Urology Devices (DHT3B)

A reference device is included in this submission as well. The reference device is the UroLift Advanced Tissue Control (ATC) System from NeoTract (K200441)

Trade Name:	NeoTract UroLift System Advanced Tissue Control (ATC) System
Common Name:	Implantable transprostatic tissue retractor system
Classification Name:	Implantable transprostatic tissue retractor system
Product Code:	PEW
Regulation Number:	876.5530
Classification:	II
Classification Panel:	Gastrorenal, ObGyn, General Hospital, and Urology Devices (OHT3) Reproductive, Gynecology and Urology Devices (DHT3B)

COMPARISON WITH THE PREDICATE DEVICE

The UroLift 2 ATC Advanced Tissue Control System is based on the UroLift 2 System platform cleared in K201837. The UroLift 2 ATC System device leverages the same platform design as the UroLift 2 System and includes a modification to the distal tip, with the addition of the ATC wings, giving the tip a larger footprint during the procedure and allowing for effective mobilization of tissue when needed.

The remainder of the device is substantially equivalent to the UroLift 2 System. The implant components, including the materials, specifications and methods of manufacture are unchanged relative to the predicate device. The system mechanics and delivery is substantially equivalent.

COMPARISON WITH THE REFERENCE DEVICE

The UroLift 2 ATC Advanced Tissue Control System described in this submission utilizes the cleared UroLift Advanced Tissue Control (ATC) System for some of the changes to the design of the UroLift 2 ATC Advanced Tissue Control System device including the redesigned distal tip of the proposed device to match the UroLift Advanced Tissue Control (ATC) geometry. The device parameters relevant to the placement of the UroLift implant are identical between the UroLift 2 ATC Advanced Tissue Control System and the UroLift Advanced Tissue Control (ATC) System.

DESIGN CONTROLS

The NeoTract Product Development Process specifies the activities and deliverables to be completed to ensure that changes do not raise any new issues of safety and/or effectiveness. The procedure includes risk management, development planning, the development of design inputs, the creation of design outputs, design verification and validation activities, design reviews, design transfer and post-market surveillance.

An analysis of all risks related to the subject device in this submission was conducted. The UroLift 2 ATC Advanced Tissue Control System does not compromise the clinical condition or safety of patients or the safety and health of users. The subject device does not affect the safety or efficacy of the UroLift Implant once delivered to the patient. The subject device does not present any new clinical risks or undesirable side-effects.

PERFORMANCE TESTING

The design requirements for the UroLift 2 ATC Advanced Tissue Control System were reviewed and non-clinical design verification testing was required to assure that the modifications of the proposed device did not impact the safe and effective use of the device. Non-clinical testing included deployment testing, compatibility with accessories, and implant, shaft, and wing performance testing. The testing was performed on devices which had undergone worst case sterilization, accelerated aging, and transit testing. The majority of the test methods were equivalent to the testing for the 510(k) cleared UroLift 2 System (K201837), and all acceptance criteria were met.

BIOCOMPATIBILITY TESTING

The UroLift 2 ATC Advanced Tissue Control System 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*. The modification addressed in this 510(k) submission introduces new materials and, therefore additional biocompatibility testing was performed.

Biocompatibility testing was performed on worst case sterilized patient contact components and included:

- Cytotoxicity testing per *ISO 10993-5:2009 – Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity*
- Sensitization Reactivity testing per *ISO 10993-10:2021, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization*
- Systemic Toxicity testing per *ISO 10993-11:2017, Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity*
- Intracutaneous Reactivity testing per *ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation*
- Material Mediated Pyrogenicity and Acute Systemic Toxicity per ISO 10993-11:2017 – *Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity*

STERILIZATION AND SHELF LIFE TESTING

The UroLift 2 ATC Advanced Tissue Control System has been validated to determine the minimum gamma irradiation dose to ensure a 10^{-6} Sterility Assurance Level (SAL). The modification addressed in the 510(k) submission may impact the product sterility because the modified component utilizes new materials and adds some geometric complexity to the device. These materials are manufactured, processed, and handled similarly to the predicate UroLift 2 device.

CONCLUSION

The testing demonstrated the NeoTract UroLift 2 ATC Advanced Tissue Control System is as safe and effective, has the same intended use, technological characteristics and principles of operation as the predicate device. Therefore, the NeoTract UroLift 2 ATC Advanced Tissue Control System is substantially equivalent to the UroLift 2 System.