



July 31, 2020

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

Re: K201837
Trade/Device Name: NeoTract[®] UroLift[®] 2 System (UL2)
Regulation Number: 21 CFR§ 876.5530
Regulation Name: Implantable transprostatic tissue retractor system
Regulatory Class: II
Product Code: PEW
Dated: June 30, 2020
Received: July 2, 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 Martha W. Betz, Ph.D.
Acting 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

Indications for Use

510(k) Number (if known)
K201837

Device Name
NeoTract® UroLift® 2 System (UL2)

Indications for Use (Describe)

The UroLift 2 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

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DATE PREPARED

30 June 2020

DEVICE INFORMATION

Trade Name: NeoTract® UroLift® 2 System (UL2)
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)

DEVICE DESCRIPTION

The UroLift System is designed to access the prostatic urethra and deliver one UroLift Implant through a lobe of the prostate. The UroLift 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 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 System (UL2), most recently cleared in K173087 under the marketing model number of UL500, is comprised of the UroLift Delivery Handle (single patient use), the UroLift Implant Cartridges (single-use) and the UroLift Implants (one implant per cartridge). Each Implant Cartridge is pre-loaded with one UroLift Implant. The Implant Cartridges fit into the Delivery Handle. Each patient procedure will use one dedicated Delivery Handle and the number of Implant Cartridges/implants necessary to perform a typical procedure (estimated 2-6

implants). The UroLift 2 System is also provided with an optional Scope Seal which enables a clinician to examine the anatomy between implant deployments without removal of the telescope from the Delivery Handle.

INTENDED USE

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.

CONTRAINDICATIONS

The UroLift 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 UL500 System by NeoTract (K173087).

Trade Name: NeoTract UroLift System (UL500)
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)

A reference device is included in this submission as well. The reference device is the UroLift UL400 System by NeoTract (K193269)

Trade Name: NeoTract UroLift System (UL400)
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 System (formerly UL500) described in this submission is substantially equivalent to the previously cleared generations of the device. The UroLift 2 System was most recently cleared in K173087; previous clearances included K172359, K162345, and K153584. Minor device modifications have been made to the UL2 Delivery System (Delivery Handle and Implant Cartridge) that do not affect the overall safety and effectiveness of the UroLift procedure. No modifications have been made to the UroLift Implant.

COMPARISON WITH THE REFERENCE DEVICE

The UroLift 2 System described in this submission utilizes the cleared UroLift System UL400 for some of the changes to the design of the device including the redesigned distal tip of the proposed device to match the UL400 geometry, as well as the expanded contraindication to increase the prostate size limitation from 80cc to 100cc. The device parameters relevant to the placement of the UroLift implant are identical between the UroLift 2 System and the UroLift System UL400.

PERFORMANCE TESTING

The design requirements for the UroLift 2 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 product performance testing, compatibility testing, and deployment testing. The testing was performed on devices which had undergone worst case sterilization and transit testing. The test methods were equivalent to the previously cleared UroLift System, and all acceptance criteria were met.

BIOCOMPATIBILITY TESTING

The UroLift 2 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* and the FDA guidance “Use of International Standard ISO 10993-1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*”. The modifications addressed in this Special 510(k) submission do not impact the UroLift Implant cleared previously. Parts of the Delivery Device (Delivery Handle and Implant Cartridge) are patient contacting. They are considered externally communicating: tissue, bone, dentin with limited (<24 hour) contact. These components were tested according to ISO 10993-1:2018. Biocompatibility testing was performed on worst case sterilized devices and included, as applicable:

- 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*
- *ISO 10993-11:2017: Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity*

STERILIZATION AND SHELF-LIFE TESTING

The UroLift System has been validated to determine the minimum gamma irradiation dose to ensure a 10^{-6} Sterility Assurance Level (SAL). Due to the modifications of the device, a new sterilization validation was performed, which included recovery, total bioburden, bacteriostasis/fungistasis, and product sterility. In addition, new dose mapping studies were completed at the sterilization sites.

Device functional testing was performed in a manner equivalent to the predicate to ensure the device functioned as intended after the stated shelf life of 12 months. Additional shelf life studies may be performed to extend the shelf life in the future using equivalent test methods.

CONCLUSION

The testing demonstrated the NeoTract UroLift 2 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 System is substantially equivalent to the predicate device.