June 7, 2021

Northgate Technologies, Inc.
Todd Gatto
Director of Quality Assurance and Regulatory Affairs
1591 Scottsdale Court
Elgin, IL 60123

Re: K202813
Trade/Device Name: AUTOLITH® URO-TOUCH 9 Fr Probe
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electro-Hydraulic Lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: May 11, 2021
Received: May 14, 2021

Dear Todd Gatto:

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.
Acting Assistant Director
DHT3B: Division of Reproductive,
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OHT3: Office of GastroRenal, ObGyn,
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202813

Device Name
AUTOLITH® URO-TOUCH 9 Fr Probe

Indications for Use *(Describe)*
The Northgate Technologies Inc. AUTOLITH®URO-TOUCH 9 Fr Probe, bipolar disposable EHL is designed to be used with the Northgate Technologies Inc. AUTOLITH®URO-TOUCH unit/generator for the fragmentation of renal calculi located in the kidneys and urinary bladder.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Northgate Technologies, Inc.

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510(k) Summary

Submitter:

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Preparation Date: June 7, 2021

Registration #: 1450997

Trade Name: **AUTOLITH® URO-TOUCH 9 Fr Probe**

Common / Usual Name: Lithotripter, Electro-Hydraulic

Classification Name:

Lithotripter, Electro-Hydraulic
21 C.F.R. 876.4480

Regulatory Class: II

Product Code(s): FFK

Rationale For Change:

Northgate is submitting this design change to the **AUTOLITH® URO-TOUCH 9 Fr Probe** in order to update compliance to the most current standards for biological safety. The materials are being updated to comply with the ISO 10993-1:2009, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing", and associated standards. The Predicate devices were classified as USP Class IV, but did not conform to the ISO 10993-1:2009 requirements.

Predicate Devices:

Northgate Technologies Inc. **AUTOLITH® URO-TOUCH 9 Fr Probe** is the same as the current **9 Fr Probe** with the exception of materials used to manufacture the probe, which are ISO 10993 compliant. The "Predicate Devices" are listed below:

A) Product – Autolith Touch; Uro Touch, For Biliary and Renal Procedures, K130368; Clearance November 15, 2013 (Primary)

Device Description:

The **Northgate Technologies Inc. AUTOLITH® URO-TOUCH 9 Fr Probe**, bipolar disposable EHL is designed to be used with the **Northgate Technologies Inc. AUTOLITH® URO-TOUCH** unit/generator for the fragmentation of calculi located in the kidneys and urinary bladder.

The Northgate Technologies Inc. **AUTOLITH® URO-TOUCH** System consists of a software controlled, electronic unit (Generator) which generates a single high-voltage pulse or a series of pulses across the tip of a flexible bipolar lithotripter probe. When discharged in 0.9% normal physiological saline solution, these pulses produce sharp, high-amplitude hydraulic shock waves that crack calculi (stones) located inside the body. They are capable of cracking calculi of virtually any size and composition. The objective is to reduce the size of the calculi so that fragments can be removed without major surgery.

The AUTOLITH® URO-TOUCH System includes the following major components:

AUTOLITH® URO-TOUCH Unit/Generator (K130368)

● Regulate the discharge voltage and repetition rate of a shot delivered to a connected extender cable and probe.

●Display the relative power delivered to the probe.

● Display the number of pulses to be delivered to the probe as requested by the operator.

● Automatically sense the existence of a plugged-in probe.

● Automatically preset start-up values for power and pulses according to the probe type.

● Automatically scale power range according to the probe type.

● Prohibit discharge of high voltage when the footswitch is activated if an extender cable/probe is not properly connected.

● Automatically compares the pulses delivered at the selected power levels and displays when to INSPECT or REPLACE PROBE.

● Displays the number of pulses delivered.

● Automatic AC Voltage Adjust. For use in all countries.

The **AUTOLITH® URO-TOUCH 9 Fr Probe** is 54 cm long and is used with a transurethral scope for fragmentation of calculi in the kidneys and urinary bladder.

The 9 Fr Probe, 54 cm long, was previously cleared by K914516 on January 7, 1992. The Extender Cable was cleared by K914517 on June 30, 1992.

Intended Use: The "Intended Use" for the **AUTOLITH® URO-TOUCH 9 Fr Probe** shall be "Fragmentation of calculi".

Indications for Use: The **Northgate Technologies Inc. AUTOLITH® URO-TOUCH 9 Fr Probe,** bipolar disposable EHL is designed to be used with the **Northgate Technologies Inc. AUTOLITH® URO-TOUCH** unit/generator for the fragmentation of renal calculi located in the kidneys and urinary bladder.

Materials: All materials used to manufacture the Northgate Technologies Inc. **AUTOLITH® URO-TOUCH 9 Fr Probe,** catalog number 9-203-0543, are not toxic and have been previously used to manufacture other medical devices.

Probe Materials: Brass
Copper

Kynar
Nylon
Polymide
Acrylated Olefin
Epoxy
Polyetheretherketone (PEEK)
These materials have been tested and **have passed** the requirements of the ISO 10993-1 Standard. Listed below are the specific tests.

Cytotoxicity
Sensitization
Irritation or Intracutaneous Reactivity
Acute Systemic Toxicity Test
Hemocompatibility
Latex-Free
DEHP Free

Performance Data: Both Design Verification and Design Validation have been completed. These documents can be found in Volumes 018 and 021.

Feature Comparison: A URO-TOUCH 9 French Probe Feature Comparison follows.

Trade/proprietary name and 510(k) number **Feature Compared**	**AUTOLITH® URO-TOUCH 9 Fr Probe**	**Primary Predicate AUTOLITH® URO-Touch 9 Fr Probe (K130368)**
Common/usual Name	Lithotripter, Electro-Hydraulic	Lithotripter, Electro-Hydraulic
Model Number	9-203-0543	9-203-0543 (72-00198-0)

Trade/proprietary name and 510(k) number **Feature Compared**	**AUTOLITH® URO-TOUCH 9 Fr Probe**	**Primary Predicate AUTOLITH® URO-Touch 9 Fr Probe (K130368)**
Intended Use	Fragmentation of calculi	Fragmentation of calculi
Indication for use	The **Northgate Technologies Inc. AUTOLITH® URO-TOUCH 9 Fr Probe,** bipolar disposable EHL is designed to be used with the **Northgate Technologies Inc. AUTOLITH URO-TOUCH** unit/generator for the fragmentation of renal calculi located in the kidneys and urinary bladder.	The **AUTOLITH® URO-TOUCH** unit is designed to be used with **Northgate Technologies Inc.** bipolar disposable EHL probes for the fragmentation of renal calculi (located in the kidneys, ureters and urinary bladder).
Diameter	**9 French (3mm)**	**9 French (3mm)**
Length	**54 cm**	**54 cm**
Materials – Tip	**Brass**	**Brass**
Materials – Outer Sheath	**INSULTAB 3/32" 714 HS WHITE**	**Alpha FIT-221-3/32"**
Power Output	**4000 PSI**	**4000 PSI**

Note: There are no feature differences with the exception of an updated Materials for ISO 10993 Compliance. Power output is discussed further in the Bench Testing section.

Differences:

The minor differences in Indications for Use between the subject device and the predicate is (1) the re-structure of the Indications statement for the subject device to be specific to the 9 French Probe in its use with the AUTOLITH URO-TOUCH generator, whereas the Indications for the predicate include the use of the

AUTOLITH URO-TOUCH generator with Northgate Technologies' bipolar disposable EHL probes more generally, and (2) the removal for use of the device in the ureters. The Northgate risk assessment suggests that the power output (4000 PSI) of the 9 French Probe poses a risk of injury (stricture or perforation) to the patient if used in the ureters and therefore it has been removed from the Indications. The Indications for Use for the subject device are therefore more restricted than the Indications of the predicate device.

The most significant difference and primary subject of this 510(k), was the change of the patient contacting material, the outer sheath material, 32-00324-0 Tubing, HS White 3/32" used on the predicate to the 32-00583-0 Tubing HS 3/32" White used in the subject device.

This type of heat shrink was also contained within the tip of the device (Part Number 32-00323-0, claimed as non-patient contacting for the predicates). Northgate changed this component to a material confirmed to be ISO 10993-compliant and updated the material to potential patient contacting due to the normal use degradation of the center conductor over the normal life of the probe. This part was replaced with the 32-00578-0 Tubing, PEEK .02" X .062" X 1".

Conclusion:

The different technological characteristics and information submitted to the FDA do not raise new questions of safety and efficacy and demonstrate that the device is at least as safe and effective as the legally marketed predicate device.