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510(k) Summary

Submitter:

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NOV 15 2013

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Preparation Date: April 25, 2013

Registration #: 1450997

Trade Name: **AUTOLITH® TOUCH** (9-202-00) / **AUTOLITH® URO-TOUCH** (9-203-00)
Lithotripters

*Note: The **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** are exactly the same devices with just one exception, a software partition that allows the unit to read resistor values in the various bipolar disposable EHL probes offered. This software difference allows Northgate Technologies to isolate the devices to use specific probes and thus market and sell the two separately labeled devices for separate specialties (Biliary and Urology). Historically, Northgate marketed a single **AUTOLITH®** device (predicate device listed below) that was used in both Biliary and Urologic applications. Although the new **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** devices are exactly the same, the ability to isolate Biliary and Urologic EHL probes to the specifically labeled units provides marketing flexibility for Northgate Technologies (pricing, targeted marketing, etc.) The*

instructions for use and the Operator's Manual for both of the new devices are essentially the same, with the only differences being the product images, the indications for use (Biliary vs. Urology) and the accessory probes available (longer probes for Biliary applications and shorter probes for Urologic applications).

Common / Usual Name: Lithotripter, Electro-Hydraulic

Classification Name: Lithotripter, Electro-Hydraulic
21 C.F.R. 876.4480

Regulatory Class: II

Product Code(s): 78FFK

Predicate Devices: Northgate Technologies Inc. **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** units operate identically, with the only difference being the intended probe lengths to be used with each device (as described above in the *Trade Name* section of this Summary). Both devices utilize the legacy **AUTOLITH®** Lithotripter unit as a predicate. The only significant differences between the new devices and the predicate **AUTOLITH®** relate to a revised user interface and more modern internal electronic components allowing for a smaller and lighter-weight design. The predicate device is:

Autolith® For Renal and Biliary Procedures, (K923822), approved, January 28, 1993.

Device Description: The **AUTOLITH® TOUCH** unit is designed to be used with Northgate Technologies Inc. bipolar disposable EHL probes for the fragmentation of biliary calculi. The **AUTOLITH® URO-TOUCH** unit is designed to be used with Northgate Technologies Inc. bipolar disposable probes for the fragmentation of renal calculi.

Both devices operate just like the legacy (predicate) **AUTOLITH®** device. The units are software-controlled, electronic devices capable of cracking calculi of virtually any size and composition. The devices are table-top units that connect to a disposable probe that is used in the working channel of an endoscope. A surgeon places the tip of the probe near the surface of the calculus/stone under endoscopic visualization. The physician then steps on a pneumatic foot pedal to activate the device. The electronic circuitry of the device generates a single high-voltage pulse or a series of pulses across the tip of the disposable flexible bipolar lithotripter probe. The discharge (in 0.9% normal physiological saline) produces sharp, high-amplitude hydraulic shockwaves that help to fragment the calculus/stone so it can be passed or removed without major surgery.

The **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** systems include the following major components:

- Base unit
- Detachable Power Cord
- Pneumatic Footswitch
- Extender Cable to connect disposable probes to unit
- Four types of Disposable Bipolar EHL Probes:
    - 250cm and 375cm 1.9Fr probes for **AUTOLITH® TOUCH**
    - 120cm (1.9Fr) and 54cm (9.0Fr) probes for **AUTOLITH® URO-TOUCH**

*Note: All accessory items (Power Cord, Pneumatic Footswitch, Extender Cable and four Disposable Probes) are the same accessories that have historically been used with the predicate **AUTOLITH®** device. The only modifications to*

accessories have been the elimination of the pre-attached ferrite core on the Extender Cable (although previously-sold Extender Cables with ferrite cores are also compatible with the new devices) and a minor modification to the Disposable Probes (change of the resistor value of the individual probe) so that the new devices can detect which type of probe is attached to the unit. These modifications have no impact on the application or efficacy of the accessories.

The **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** devices, just as the predicate **AUTOLITH®** device, will:

- Regulate the discharge voltage and repetition rate of a pulse 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 compare the pulses delivered at the selected power levels and display when to inspect or replace the probe.
- Display the number of pulses delivered.

All accessories are cleared medical devices that may be used with this device. The 1.9fr 120cm Probe was cleared by K914514 on January 6, 1992, and the 9fr 54cm Probe was cleared by K914516 on January 7, 1992. The 1.9fr 250cm Probe was cleared by

	K913955 on November 29, 1991. The Extender Cable was cleared by K914517 on June 30, 1992. The new units have the same performance characteristics as the predicate device. The only significant modified technological characteristics of the new **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** as compared to the predicate **AUTOLITH®** device include a revised user interface and more modern internal electronic components allowing for a smaller and lighter-weight design.
Intended Use:	The "Intended Use" for the **AUTOLITH® TOUCH** and **AUTOLITH® URO TOUCH** as well as the legacy **AUTOLITH® Electro-Hydraulic Lithotripters** shall be "Fragmentation of Calculi."
Indications for Use:	The **AUTOLITH® TOUCH** unit is designed to be used with Northgate Technologies Inc. bipolar disposable EHL probes for the fragmentation of biliary calculi. The **AUTOLITH® URO-TOUCH** unit is designed to be used with Northgate Technologies Inc. bipolar disposable probes for the fragmentation of renal calculi.
Materials:	All materials used to manufacture the Northgate Technologies Inc. **AUTOLITH ® TOUCH,** catalog number 9-202-00 (115 VAC /100 VAC/ 230 VAC), and **AUTOLITH® URO-TOUCH,** catalog number 9-203-00 (115 VAC / 100 VAC / 230 VAC) and probes are not toxic and have been previously used to manufacture other medical devices.
Probe Materials:	Stainless Steel Polymide Copper Kynar Nylon Polyolefin Epoxy

These materials have been tested and **have passed** the requirements of the ISO 10993-1 Standard. Listed below are the specific tests.

Cytotoxicity
Sensitization (Kligman Maximization)
Irritation or Intracutaneous Reactivity
Acute Systemic Toxicity Test
Pyrogenicity
Latex
DEHP

Performance Data: Both Design Verification and Design Validation have been completed.

Feature Comparison: The new units have the same performance characteristics as the predicate device. The only modified technological characteristics of the new **AUTOLITH® TOUCH** and **AUTOLITH® URO-TOUCH** as compared to the predicate **AUTOLITH®** device include the following:

- New units include an **easy-to-use color touchscreen user interface**, rather than the membrane switches and segmented digital displays from the predicate device. The new interface has also allowed for multi-language displays and selections.
- New units utilize **more modern electronic components** that have allowed for a smaller and lighter-weight platform.
- Additionally, there are some very minor modifications that have been implemented to simplify use of the device:
    - New units have a universal switching power supply; **that of a type used on other cleared Northgate Technologies Inc. devices,** that auto-adjusts for various voltage requirements. The predicate device

had multiple part numbers for units that were intended for specific voltage requirements.

- New units have simplified selection of High/Medium/Low pulse power delivery, rather than power selection ranges from 10%-100% (in 10% increments) utilized by the predicate device
- New units force the replacement of a disposable probe when the 'Replace Probe' message appears, whereas the predicate device allowed continued usage of the probe.
- New units have standardized the frequency of the pulse firings to 30hz, whereas the predicate device allowed for some little used, user modification and customization of the frequency.
- New units allow for selectable (adjustable) and storable user preferences for start-up values of power and pulse settings.

Substantial Equivalence:

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.

Non-clinical bench tests have been performed to prove substantial equivalence in the overall performance characteristics of the device. Below is a summary of how this testing supports the claim of substantial equivalence:

The main design requirement for the **AUTOLITH® TOUCH / AUTOLITH® URO-TOUCH** was to produce the same output as the current device. The design goal was to produce a modern, simpler, and more reliable version of the current device. To those

ends, it was necessary to ensure the new device produces the same pressure wave output as the current **AUTOLITH®** device. The pressure wave output is completely dependent on the voltage waveform applied to the probe. By design, the 6kV output capacitor is the main contributor in determining the voltage waveform applied to the probe. The new device incorporates the same 6kV output capacitor as the current device and uses modern circuitry to produce the same voltage waveform for the probe. Comparison testing was performed to prove that the output of the Autolith Touch is, in fact, the same as the output of the current device. These tests compared both the voltage waveform output applied to the probe as well as the actual pressure wave output from the probe that will be applied to the target stone.

Date Prepared: April 25, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 15, 2013

Northgate Technologies, Inc.
Casey Kurek
Regulatory Manager
1591 Scottsdale Court
Elgin, IL 60123

Re: K130368
Trade/Device Name: AUTOLITH® TOUCH / AUTOLITH® URO-TOUCH
Regulation Number: 21 CFR§ 876.4480
Regulation Name: Electrohydraulic lithotriptor
Regulatory Class: II
Product Code: FFK
Dated: September 20, 2013
Received: October 4, 2013

Dear Casey Kurek,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K130368:

Device Name: **AUTOLITH ® TOUCH / AUTOLITH® URO-TOUCH**

Indications for Use:

The **AUTOLITH® TOUCH** unit is designed to be used with Northgate Technologies Inc. bipolar disposable EHL probes for the fragmentation of biliary calculi. The **AUTOLITH® URO-TOUCH** unit is designed to be used with Northgate Technologies Inc. bipolar disposable EHL probes for the fragmentation of renal calculi.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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(Posted November 13, 2003)