February 27, 2018

NxThera, Inc.
Kathy Simpson
VP Quality and Regulatory Affairs
7351 Kirkwood Land North, Suite 138
Maple Grove, MN 55369

Re: K180237
Trade/Device Name: Rezūm System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS
Dated: January 25, 2018
Received: February 1, 2018

Dear Kathy Simpson:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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

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)*
K180237

Device Name
Rezūm System

Indications for Use *(Describe)*
The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume ≥ 30cm3 and ≤ 80cm3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

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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510(k) Summary

I. SUBMITTER

NxThera, Inc.
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Maple Grove, MN 55369

Phone: (763) 515-0404
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Contact Person: Kathy Simpson
Date Prepared: January 18, 2018

II. DEVICE

Name of Device:	Rezūm® System
Common or Usual Name:	Vapor Ablation System
Classification Name:	Endoscopic electrosurgical unit and accessories (21 CFR §876.4300)
Regulatory Class:	II
Product Code:	KNS

III. PREDICATE DEVICE

Rezūm System, K160417

IV. DEVICE DESCRIPTION

The Rezūm System consists of a reusable Generator and a sterile Delivery Device Kit consisting of one Delivery Device with cable and tubing, one syringe, one spike adaptor, and one 50mL sterile water vial. The Delivery Device is EtO sterilized.

The Rezūm System converts water into vapor outside of the body with the vapor delivered to the prostate tissue via a needle within the sterile Delivery Device. The vapor ablates the targeted tissue within the prostate via thermal ablation as energy is transferred from the vapor to the prostate tissue. The amount of vapor delivered is controlled by a Radiofrequency (RF) Generator which also control the amount of saline flush used to cool the urethra during the treatment.

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V. INDICATIONS FOR USE

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. It is indicated for men ≥ 50 years of age with a prostate volume ≥ 30cm^3 and ≤ 80cm^3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following technological elements that remain equivalent between the two devices:

- Cystoscope used within the Delivery Device to visualize the target treatment area
- Device is inserted into the urethra to reach the targeted prostate tissue
- Generation of water vapor via a specific caloric / energy requirement
- Thermal ablation of the prostate tissue
- Use of saline flush to cool the urethra during treatment

The following technological differences exist between the subject and predicate devices:

- Design enhancements of the user interface:
    - Reduced device handle envelope distance, improve handle angle and improve fit and feel
    - Changed needle delivery and retraction mechanism from mechanical to electrical

- Design changes to enhance manufacturability and reliability of the Delivery Device:
    - Change vapor coil material to a more efficient material
    - Relocate temperature monitoring on vapor coil
    - Group switching functions on one printed circuit board
    - Cable changes including a plastic non-locking connector to improve manufacturability
    - Replace prior adhesive with equivalent adhesive
    - Removal of the device rotation capability

- Design changes to accommodate device updates, manage component obsolescence, enhance manufacturability and reliability of the Generator:
    - Update circuit boards and software for new electrical needle delivery and retraction mechanism, to manage obsolescence and improve manufacturability
    - Update RF power supply to accommodate new vapor coil material

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- Move ESD protection from Device to Generator
- Update wiring and connectors for manufacturability and servicing

VII. PERFORMANCE DATA

The modifications made to the subject Rezūm System have been tested to ensure compliance to the initial device specifications. Based on the change assessment, the following design verification tests were repeated on the C2 Delivery Device. The test methods used were the same as those submitted for the predicate device:

- Dimensional
- Tensile / bond strength tests
- Full Functional tests
- Fluid resistance
- Calorimetry tests
- Corrosion resistance
- Packaging and distribution testing
- Sterility validation
- Shelf-life aging
- Software verification and validation
- Hardware tests
- Electrical safety testing (per IEC 60601-1)
- Electromagnetic compatibility testing (per IEC 60601-1-2)

The conclusion of the performance assessments demonstrate that the device continues to function as intended in a manner equivalent to the predicate device, and that there are no new issues of safety or effectiveness with the implementation of the above listed modifications.

VIII. CONCLUSION

Based on the test data and other characteristics of the subject device as compared to the predicate, the modified Rezūm System is substantially equivalent to its predicate Rezūm System.