



Food and Drug Administration
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April 19, 2016

NxThera, Inc.
Julie Bodmer
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Ave North, Suite 63
Brooklyn Park, MN 55428

Re K160417
Trade/Device Name: Rezūm System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: February 12, 2016
Received: February 16, 2016

Dear Julie Bodmer,

This letter corrects our substantially equivalent letter of March 17, 2016

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 contact the Division of Industry and Consumer Education 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,


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

Indications for Use

510(k) Number (if known)

K160417

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 $\geq 30\text{cm}^3$ and $\leq 80\text{cm}^3$. 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.

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8 510(K) SUMMARY

8.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: February 12 2016

8.1.1 CONTACT INFORMATION

Submitter/Manufacturer **NxThera Inc**
7351 Kirkwood Lane N, Suite 138
Maple Grove, MN 55369 USA
Tel: 763-515-0404
Fax: 763-515-2084

Primary Submission Contact Julie Bodmer
Regulatory Consultant, Libra Medical, Inc.
8401 73rd Ave North, Suite 63
Brooklyn Park, MN 55428
Cell: 612-910-3412
Fax: 763-477-6357
Email: jbodmer@libramed.com

Secondary Submission Contact Sew-Wah Tay
Regulatory Consultant, Libra Medical, Inc.
8401 73rd Ave North, Suite 63
Brooklyn Park, MN 55428
Cell: 612-801-6782
Fax: 763-477-6357
Email: swtay@libramed.com

8.1.2 DEVICE INFORMATION

Trade Name	Rezūm System
Common Name	Vapor BPH Ablation Device
Classification Name	Endoscopic electrosurgical unit and accessories
Classification Regulation	876.4300
Class	II
Panel	Gastroenterology/Urology
Product Code	KNS

8.2 PREDICATE DEVICE

The modified device is substantially equivalent to the NxThera Rezūm System (K150786).

8.3 DEVICE DESCRIPTION

The reusable Rezūm Generator is provided with the following reusable components:

- Generator
- One Power Cord

The Rezūm Delivery Device Kit contains the following disposable components:

- One sterile Delivery Device with cable and tubing
- One sterile Syringe
- One sterile Spike Adaptor
- One 50 ml Sterile Water Vial

Additional spike adaptor and syringe accessory is provided as an Accessory Pack.

8.4 INTENDED USE

The Rezūm System is intended to ablate prostate tissue.

8.5 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 $\geq 30\text{cm}^3$ and $\leq 80\text{cm}^3$. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

8.6 TECHNOLOGICAL CHARACTERISTICS

The device converts water into vapor outside of the body and the vapor is 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 an RF Generator which also controls the amount of saline flush used to cool the urethra.

The differences between this device and the predicate are minor and include replacing two minor parts due to obsolescence and a change to a higher viscosity lubricant to improve the ease of application during manufacture. The only technological difference lies in the use of a vented drip chamber for the saline flush tubing instead of the predicate non-vented drip chamber. This change allows for the use of hard plastic bottles of saline in addition to saline bags. The technological characteristics remain equivalent to the predicate device.

8.7 PERFORMANCE DATA

The predicate Rezūm System has been tested and meets all its physical and performance specifications on the bench including:

- Dimensions
- Tensile strength tests
- Full functional tests

- Calories tests
- Hardware tests
- Software verification and validation
- Packaging tests
- Distribution tests

The device has also been tested in 3 clinical studies: 65 patients in the feasibility and pilot open label studies and in a 197 patient randomized placebo controlled study. All these studies showed that the device is safe and effective.

The design changes to the candidate Rezūm System have been tested to ensure compliance to the initial specifications. Based on the change assessment, the following design verification tests were repeated on the Delivery Device. The test methods used are the same as those submitted for the predicate.

- Tensile/Bond strength tests including the new vented drip chamber and flush tubing before and after 12-month aging
- Tubing tests (tubing compliance, kink, burst, etc.)
- Functional tests (temperature, pressure, etc.)
- Calories tests
- Biocompatibility

The conclusion of the assessments demonstrates that the device continues to function as intended. Testing showed that the modified device is as safe and effective as the predicate.

8.8 SUBSTANTIAL EQUIVALENCE

The modified NxThera Rezūm System is substantially equivalent to the NxThera Rezūm System (K150786). It has the same intended use for thermal ablation of BPH tissue. The generator and delivery device remain the same.

8.9 CONCLUSION

Based on the test data and the same intended use, the modified Rezūm System is found to be substantially equivalent to its predicate.