



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

September 12, 2016

NxThera, Inc.
% Sew-Wah Tay, Ph.D.
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Avenue North, Suite 63
Brooklyn Park, MN 55428

Re: K150786
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: August 21, 2015
Received: August 24, 2015

Dear Sew-Wah Tay:

This letter corrects our substantially equivalent letter of August 27, 2015.

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" (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 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,

For Division

Douglas Silverstein -S
2016.09.12 16:11:58 -04'00'

Benjamin 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		Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
Indications for Use		
510(k) Number (<i>if known</i>)		
K150786		
Device Name:		
Rezūm System		
Indications for Use (<i>describe</i>)		
<p>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.</p>		
Type of Use (<i>select one or both, as applicable</i>)		
<input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D)	<input type="checkbox"/> Over-The-Counter Use (Part 21 CFR 801 Subpart C)	
CONTINUE ON A SEPARATE PAGE IF NEEDED		
<p>This section applies only to requirements of the Paperwork Reduction Act of 1995 *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff <i>PRAStaff@fda.hhs.gov</i></p> <p style="text-align: center;"><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."</i></p>		

1 510(K) SUMMARY (K150786)

1.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: June 12 2015

1.2 CONTACT INFORMATION

Primary Submission Contact Sew-Wah Tay, PhD
Regulatory Consultant,
Libra Medical Inc.

Secondary Submission Contact Julie Bodmer
Regulatory Consultant,
Libra Medical Inc.

1.3 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

1.4 510(K) TYPE AND REASON FOR SUBMISSION

This 510(k) is a traditional 510(k) and is submitted to obtain marketing clearance for a new device – the Rezūm System.

1.5 PREDICATE DEVICE

The Rezūm System is substantially equivalent to the Medtronic Prostiva devices (K113380 and K142248).

1.6 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.

1.7 INDICATIONS FOR USE / INTENDED 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.

1.8 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.

1.9 PERFORMANCE DATA

The Rezūm System has been tested to meet the FDA 2010 BPH guidance where applicable for preclinical and clinical testing.

The 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

In addition, the Delivery Device was tested for biocompatibility per ISO 10993-1 for short duration contact with tissue and mucosal membrane (<24 hours). The device is sterilized by ethylene oxide to an SAL 10^{-6} level. These performances are similar to that described by the predicate device. The testing showed that the device meets specifications before and after aging indicating that the device is as safe and effective as the predicate device.

The device has also been tested in 3 clinical studies to evaluate the safety and effectiveness of the Rezūm device: 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.

1.10 SUMMARY OF CLINICAL DATA

1.10.1 REZŪM FIM OPTIMIZATION STUDY

Fifteen subjects were enrolled in one site in this study to determine the optimum settings and vapor dosage for the Rezūm System. Subjects were evaluated for outcomes, adverse events and prostate and lesion sizes at 1 week, 1 month, 3 months and 6 months.

Fifteen subjects were enrolled and treated in this study with 14 subjects having 6 months follow up data. All procedures were completed successfully and there were no unanticipated adverse event. The outcomes for the subjects were equivalent for the full range of energy tested although the higher energy group exhibited more acute AE. Site reported AE early in the study and was typical for thermal ablation of the prostate. Rapid IPSS improvement was observed at 1 month and continues to be improving through 6 months and 12 months.

1.10.2 REZŪM I PILOT STUDY

This is an open label, single arm study involving 3 centers, two in Europe and one from Latin America. A total of 50 patients were enrolled in this study, 45 of whom were enrolled in the two European sites. Only one energy level was used in this study. The IPSS improvement is consistent with the results from Rezūm FIM Optimization Study and improvements in IPSS persist through the 2 year follow up. At month 3, 6, 12 and 24 months, more than 80% of the subjects treated were responders for all the time period. There were no unanticipated adverse events with most of the reported adverse event related to LUTS symptoms and occurred in the acute healing phase.

1.10.3 REZŪM II PIVOTAL STUDY

This is a blinded, 2:1 randomized placebo control study. 197 subjects were enrolled in this study. 136 subjects were randomized to the treatment arm and 61 were assigned to the control arm. 83.6% of the control subjects crossed over to the treatment arm. The rest of the subjects either did not qualify at the time of the crossover or exited the study.

The primary objective is to establish the safety and effectiveness of the device. On an intention to treat basis, the results showed that the device is safe ($p < 0.0001$). The effectiveness as measured by IPSS. At 3 months, the effectiveness of the Rezūm System was superior to the control group ($p < 0.001$). The long term effectiveness was measured at 6 and 12 months by comparing the IPSS to the subjects' baseline. At 6 months, 75% of the subjects were responders ($p < 0.0001$) and at 12 months, 77% of the subjects were responders ($p < 0.0001$).

There were no unanticipated adverse events.

1.11 SUBSTANTIAL EQUIVALENCE

The Rezūm System is substantially equivalent to the Prostiva Device (K113380/K142248). It has the same intended use for thermal ablation of BPH tissue. The test and clinical data showed that the technological difference between the Rezūm and its predicate do not raise safety and efficacy issues. The Rezūm II randomized placebo controlled clinical trial data showed that the device is effective in relieving the symptoms of BPH and does not raise new questions of safety.

1.12 CONCLUSION

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