June 11, 2025

Boston Scientific Corporation
Joseph Tabor
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K250584
Trade/Device Name: Rezum System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: February 27, 2025
Received: May 6, 2025

Dear Joseph Tabor:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250584

Device Name

Rezūm System

Indications for Use *(Describe)*

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia(BPH). It is indicated for men ≥ 50 years of age with a prostate volume 30 cm3 ≤ 150 cm3. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

A. Date Prepared

This 510(k) summary was prepared February 27, 2025

B. Submitter

Boston Scientific Corporation
Urology Division
100 Boston Scientific Way
Marlborough, MA 01752

C. Contacts

Joseph Tabor
Regulatory Affairs Specialist II
Joseph.Tabor@bsci.com
(508) 382-0313

Alternate:

Cody Johnson
Regulatory Affairs Manager
Cody.Johnson@bsci.com
(952) 930-5736

D. Subject Device

Trade Name	Rezūm System
Common Name	Vapor Ablation Device
Regulation Name	Endoscopic electrosurgical unit and accessories
Regulation Number	21 CFR 876.4300
Classification	Class II
Product Code	KNS

E. Predicate Device

Trade Name	Rezūm System
Common Name	Vapor Ablation Device
Regulation Name	Endoscopic electrosurgical unit and accessories
Regulation Number	21 CFR 876.4300
Classification	Class II
Product Code	KNS
510(k) Submitter/Holder	Boston Scientific Corporation
510(k) #/Clearance Date	K191505/cleared August 2, 2019

510(k) Summary

F. Device Description

The Rezūm System is designed to treat patients with bothersome urinary symptoms associated with benign prostatic hyperplasia (BPH). The Rezūm System utilizes radiofrequency current to generate "wet" thermal energy in the form of water vapor, which is then injected into the transition zone and/or median lobe of the prostate tissue in controlled 9-second doses. The vapor that is injected into the prostate tissue rapidly disperses through the interstitial space between the tissue cells. As the vapor cools, it condenses immediately on contact with tissue and the stored thermal energy is released, denaturing the cell membranes and causing cell death.

The denatured cells are absorbed by the body, which reduces the volume of prostate tissue adjacent to the urethra. The vapor condensation process also causes a rapid collapse of vasculature in the treatment zone, resulting in a bloodless procedure.

Following thermal therapy for BPH, small pieces of coagulated tissue may slough off and be expelled via urination. This sloughing process may continue for a few months post-procedure depending on the rate of healing.

The Rezūm System consists of the following:

- Rezūm Generator – reusable, non-sterile capital equipment, provided with one power cord
- Rezūm Delivery Device Kit – sterile, single-use kit containing the following disposable components:
    - One sterile Delivery Device with cable and tubing
    - One sterile syringe
    - One sterile spike adaptor
    - One sterile water vial

G. Intended Use/Indications for Use

The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with benign prostatic hyperplasia (BPH). It is indicated for men ≥ 50 years of age with a prostate volume 30 cm^3 ≤ 150 cm^3. The Rezūm System is also indicated for treatment of prostate with hyperplasia of the central zone and/or a median lobe.

H. Technological Characteristics Compared to the Predicate Device

The technological characteristics of the proposed (subject) Rezūm System are identical to those of the predicate device. There are no changes to any device features. The only change is a modification to the Indications for Use to expand the prostate volume upper limit from ≤ 80 cm^3 to ≤ 150 cm^3. The change in Indications for Use does not create a new intended use. The predicate and the proposed Rezūm System are both intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH. The modification to the Indications for Use is supported by manufacturer-sponsored and independent clinical studies and the clinical evidence demonstrates that there are no new safety or effectiveness concerns regarding use of the Rezūm System in patients with prostates >80 cm^3 and ≤150 cm^3.

I. Substantial Equivalence

The proposed Rezūm System is substantially equivalent to the predicate Rezūm System (K191505). The proposed and predicate Rezūm System are both intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH, and the modification to the

510(k) Summary

Indications for Use does not introduce any new safety or effectiveness concerns. The Rezūm System intended use, principle of operation and technological characteristics remain the same.

J. Performance Data

The Indications for Use modification to the proposed Rezūm System has been evaluated in comparison to the predicate device. The expanded indication is supported by a systematic review and meta-analysis of clinical studies that examined safety and effectiveness of the Rezūm System in symptomatic BPH patients with prostate volumes >80 cm^3 and compared outcomes to patients with prostate volumes ≤80 cm^3. In addition, data from a manufacturer-sponsored prospective, non-randomized, single-arm study that evaluated safety and effectiveness of the Rezūm System in patients with prostate volumes >80 cm^3 and ≤150 cm^3 was compared to data from the Rezūm System pivotal clinical study. The clinical evidence showed overall comparable results between patients with prostate volumes >80cm^3 and ≤80 cm^3. Significant and similar improvements in functional and quality of life outcomes were demonstrated in both patient populations, with no negative impact to sexual function. Patients with prostate volumes >80 cm^3 had generally similar rates of adverse events, including serious complications. No unexpected adverse events were reported, and all adverse events were consistent with those reported in the Rezūm System pivotal clinical study. Use of the proposed device in the expanded patient population does not result in any new concerns of safety or effectiveness.

K. Conclusion

Based on the intended use, technological characteristics, and the clinical evidence presented in this submission to support use of the device in the expanded patient population, the Rezūm System is substantially equivalent to the predicate device.