November 26, 2025

Francis Medical, Inc.
% Alexia Haralambous
Director, Regulatory Affairs
RQM+
2790 Mosside Blvd, #800
Monroeville, Pennsylvania 15146

Re: K252388
Trade/Device Name: Vanquish Water Vapor Ablation Device
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: July 31, 2025
Received: October 29, 2025

Dear Alexia Haralambous:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252388 ?

Please provide the device trade name(s). ?

Vanquish Water Vapor Ablation Device

Please provide your Indications for Use below. ?

The Vanquish Water Vapor Ablation System is indicated for the thermal ablation of targeted prostate tissue via a transurethral approach.

Please select the types of uses (select one or both, as applicable). ?

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K252388

510(k) Summary

Prepared on: 2025-11-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Francis Medical, Inc.
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Applicant Contact Telephone	612-910-9790
Applicant Contact	Mr. Mike Kujak
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Correspondent Contact Telephone	267-778-5114
Correspondent Contact	Ms. Alexia Haralambous
Correspondent Contact Email	aharalambous@rqmplus.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vanquish Water Vapor Ablation Device
Common Name	Endoscopic electrosurgical unit and accessories
Classification Name	Unit, electrosurgical, endoscopic (with or without accessories)
Regulation Number	876.4300
Product Code(s)	KNS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K150786	Rezūm System	KNS

Device Description Summary

21 CFR 807.92(a)(4)

The Vanquish Water Vapor Ablation System provides a method of focal thermal ablation that utilizes the high energy stored in water vapor to target prostate tissue. In a minimally invasive transurethral outpatient procedure performed under transrectal ultrasound (TRUS) guidance, sterile water is heated within the system and converted into vapor. This vapor is then delivered through small emitter holes at the distal end of a transurethral needle into the prostate tissue.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Vanquish Water Vapor Ablation System is indicated for the thermal ablation of targeted prostate tissue via a transurethral approach.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Both the subject and predicate devices are intended for transurethral ablation of prostate tissue. Therefore, the devices have the same intended use.

Technological Comparison 21 CFR 807.92(a)(6)

Both the subject and primary predicate device are transurethral ablation devices for prostate tissue which use water vapor as the source of ablation energy. Both are intended for partial gland ablation using the same delivery mechanism. However, they slightly differ in ablation energy levels, and the subject Vanquish device includes a stabilization system and a needle guidance system which the predicate Rezūm device does not have. Overall, the principle of operation, mechanism of action, and conditions of use between the subject Vanquish and predicate Rezūm devices are identical.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Francis Medical conducted functional performance bench testing, biocompatibility testing, software verification & validation, cybersecurity testing, sterilization validation, electrical safety and electromagnetic compatibility testing on the Vanquish system and components and provided the results as part of this submission to support the proposed indications for use.

The performance of the Vanquish System is supported by the manufacturer sponsored VAPOR 2 (NCT05683691) pivotal study, a prospective, single-arm clinical study of an intermediate risk prostate cancer patient population to evaluate the safety and effectiveness of the Vanquish System to ablate targeted prostate tissue per the FDA Guidance Clinical Investigations for Prostate Tissue Ablation Devices.

The VAPOR 2 study is being conducted in compliance with ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice. A total of 235 patients were treated with the Vanquish System at 26 sites in the United States from July 2023 to February 2025. An interim analysis of the first 110 patients treated with the Vanquish System followed to one year supports safety and effectiveness performance for this 510(k) submission.

The VAPOR 2 study interim effectiveness endpoints per FDA Guidance are reported as follows using an intent-to-treat (ITT) approach in 110 focally treated subjects:
- Biopsy Results: with worst case imputation, 74% of subjects (81/110) show negative biopsy at six months in targeted treatment field (two-sided exact 95% confidence interval: 64% to 82%).
- Prostate Volume Reduction: average prostate volume reduction at 6-months for 110 subjects as measured by MRI is 21% (±13% standard deviation)
- PSA Reduction for 108 subjects at 12-months is 52% (± 28% standard deviation)

The VAPOR 2 study interim safety endpoints per FDA Guidance are reported in the clinical study report attached to this submission. Safety and effectiveness data were collected at enrollment, Vanquish treatment, and follow-up visits at 7, 30, 90, 180, and 365 days. Subjects are being assessed for adverse events throughout the study.

The VAPOR 2 study interim safety results are summarized as follows for 110 focally treated subjects:
- No unanticipated adverse device effects (UADE) were reported,
- No serious device-related adverse events were reported,
- Nearly all (94%) reported adverse events were non-serious, and
- Nearly all (96%) device and / or procedure-related adverse events were mild to moderate (CTCAE 1 or 2).

The VAPOR 2 study confirms that the Vanquish System is safe and effective for the ablation of targeted prostate tissue. The use of the proposed device does not result in any new concerns about safety or effectiveness compared to the predicate device.

Based on the intended use, technological characteristics, and the non-clinical and clinical evidence presented in this submission, the Vanquish System is substantially equivalent to the predicate device.