

K252388 Vanquish Water Vapor Ablation DeviceNov 26, 2025
118 days to decisionK252388 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jul 31, 2025
Decision date	Nov 26, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Francis Medical, Inc.
Location	Maple Grove, MN, US
Contact	Mike Kujak
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Alexia Haralambous

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT05683691**Water Vapor Ablation for Localized Intermediate Risk Prostate Cancer**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	400 patients (estimated)
Study sites	25 sites
Condition studied	Prostate Cancer
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 1, 2029
Sponsor	Francis Medical Inc. (Industry)

Primary outcome

Primary Effectiveness Endpoint

Secondary outcome

Key Secondary Endpoint

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05683691