

K253525 Urocross Expander System (Model Numbers ES2018 and ES3025)Mar 12, 2026
119 days to decisionK253525 · Product code: **QKA** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253525/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporarily-placed Urethral Opening System For Symptoms Of Benign Prostatic Hyperplasia (QKA)
Date received	Nov 13, 2025
Decision date	Mar 12, 2026
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Prodeon Medical, Inc.
Location	Sunnyvale, CA, US
Contact	Elaine Aplao
510(k) history	2 submissions · 2 cleared · 2025-2026

CLINICAL EVIDENCE - NCT05400980**Expander-2 Trial: Randomized Study to Evaluate Safety & Efficacy of the Urocross® Expander System & Retrieval Sheath**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	240 patients (estimated)
Study sites	2 sites
Condition studied	Benign Prostatic Hyperplasia
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Dec 1, 2028
Sponsor	Prodeon Medical, Inc (Industry)

Primary outcome

Safety of Urocross Expander Implant

Secondary outcome

Percent change in Total IPSS for subjects randomized to the Urocross Implant

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05400980