FDA 510(k) Premarket Notification

CLEARED

K261342 Urocross Expander System (UES-2018-C1)

Jun 22, 2026
60 days to decision

K261342 · Product code: **QKA** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k261342/

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	Apr 23, 2026
Decision date	Jun 22, 2026
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Prodeon Medical, Inc.**
Location	Sunnyvale, CA, US
Contact	Elaine Aplaon
510(k) history	3 submissions · 3 cleared · 2025-2026