

K252572 Prodeon Urethral Sheath SystemOct 7, 2025
54 days to decisionK252572 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k252572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Aug 14, 2025
Decision date	Oct 7, 2025
Days to decision	54 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 Aplaon
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252572/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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