FDA 510(k) Premarket Notification

K252572 Prodeon Urethral Sheath System

CLEARED

Oct 7, 2025
54 days to decision

K252572 · Product code: **FED** · Gastroenterology & Urology
Source: 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