

K240514 AMT Low-Profile Suprapubic Catheter & Drainage SetNov 1, 2024
253 days to decisionK240514 · Product code: **KOB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k240514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Suprapubic (and Accessories) (KOB)
Date received	Feb 22, 2024
Decision date	Nov 1, 2024
Days to decision	253 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Applied Medical Technology, Inc.
Location	Brecksville, OH, US
Contact	Jennifer Hazou
Website	https://www.amtinnovation.com
510(k) history	25 submissions · 18 cleared · 1998-2026

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