

**K192577 Actreen Hi-Lite Intermittent Urinary Catheters**May 7, 2020  
231 days to decisionK192577 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k192577/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Sep 19, 2019
Decision date	May 7, 2020
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>B.Braun Medical, Inc.</b>
Location	Plymouth, MN, US
Contact	Anita J. Nemeth
Website	<a href="http://www.bbraunusa.com/">http://www.bbraunusa.com/</a>
510(k) history	148 submissions · 145 cleared · 1993-2025

B.Braun Medical, Inc. is a leading medical technology company specializing in infusion therapy, vascular access, and hospital-based medical devices. The company operates with a manufacturing facility in Plymouth, Massachusetts. B.Braun Medical has maintained a strong FDA 510(k) regulatory record since 1993. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2025 demonstrate continued innovation in infusion pumps, IV catheters, and administration sets for general hospital use. The company's cleared device portfolio focuses on smart ...