FDA 510(k) Premarket Notification

CLEARED

K180801 Actreen Hi-Lite Cath, Actreen Hi-Lite Set

Nov 5, 2018
222 days to decision

K180801 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Mar 28, 2018
Decision date	Nov 5, 2018
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**B.Braun Medical, Inc.**
Location	Plymouth, MN, US
Contact	Anita J. Nemeth
Website	http://www.bbraunusa.com/
510(k) history	149 submissions · 146 cleared · 1993-2026

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 ...