FDA 510(k) Premarket Notification

CLEARED

K183253 ValPro 2 Plus, VaPro 2 Plus Pocket

Dec 18, 2018
27 days to decision

K183253 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Nov 21, 2018
Decision date	Dec 18, 2018
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hollister Incorporated**
Location	Libertyville, IL, US
Contact	Michelle Schiltz-Taing
Website	http://www.hollister.com/
510(k) history	14 submissions · 14 cleared · 2011-2025

Hollister Incorporated specializes in ostomy, continence, and critical care products with a manufacturing facility in Libertyville, US. The company serves patients and healthcare professionals globally across multiple therapeutic areas. Hollister has received FDA 510(k) clearances from total submissions since 2011. The company's regulatory focus centers on Gastroenterology & Urology devices, with the most recent clearance in 2025. This demonstrates sustained innovation and active market engagement in continence care solutions. Recent cleared devices include intermittent c...