

K180824 VaPro 2 Intermittent CatheterJun 22, 2018
84 days to decisionK180824 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Mar 30, 2018
Decision date	Jun 22, 2018
Days to decision	84 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...
