FDA 510(k) Premarket Notification

K141642 VAPRO INTERMITTENT CATHETER

CLEARED

Aug 22, 2014
64 days to decision

K141642 · Product code: **GBM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k141642/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Jun 19, 2014
Decision date	Aug 22, 2014
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hollister Incorporated**
Location	Libertyville, IL, US
Contact	JEANNE LEE
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...