

K183335 Medline Poly-Cath Red Polymer Urethral CatheterJun 12, 2019
191 days to decisionK183335 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k183335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Dec 3, 2018
Decision date	Jun 12, 2019
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Dinah Rincones
510(k) history	238 submissions · 234 cleared · 1977-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183335/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026