

**K033477 HYDROPHILIC-ANTIBACTERIAL INTERMITTENT
CATHETER, INTERMITTENT CATHETER CLOSED SYSTEM KIT**Jun 10, 2004
220 days to decisionK033477 · Product code: **MJC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k033477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (antimicrobial) And Accessories (MJC)
Date received	Nov 3, 2003
Decision date	Jun 10, 2004
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rochester Medical Corp.
Location	Rochester, MN, US
Contact	ROB ANGLIN
510(k) history	13 submissions · 13 cleared · 1990-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033477/>. 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 9, 2026