

**K983511 SOFT-LINE IJ DOUBLE LUMEN CATHETER 11.5FR X
12CM, SOFT-LINE IJ DOUBLE LUMEN CATHETER 11.5FR X
15CM, SOFT-LINE LUMEN CATH**

Jun 8, 1999
244 days to decision

K983511 · Product code: **MPB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k983511/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Hemodialysis, Non-implanted (MPB)
Date received	Oct 7, 1998
Decision date	Jun 8, 1999
Days to decision	244 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Components, Inc.
Location	Mchenry, IL, US
Contact	JEANNE M CUSH
510(k) history	63 submissions · 55 cleared · 1980-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k983511/> 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 May 26, 2026