

K801966 HEMO-CATH II KIDNEY DIALYSIS CATHETERSep 26, 1980
38 days to decisionK801966 · Product code: **FIE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k801966/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Aug 19, 1980
Decision date	Sep 26, 1980
Days to decision	38 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k801966/> 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