FDA 510(k) Premarket Notification

K000070 FLOCATH

CLEARED

Feb 18, 2000
39 days to decision

K000070 · Product code: **KOD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k000070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Jan 10, 2000
Decision date	Feb 18, 2000
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rusch Intl.**
Location	Jeffrey, NH, US
Contact	KARENANN J BROZOWSKI
510(k) history	43 submissions · 43 cleared · 1995-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k000070/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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