FDA 510(k) Premarket Notification

K896122 AMNICATHDL(TM) DT-IUPC2 DUAL LUMEN TRANS. TIPPED

CLEARED

Jan 19, 1990
87 days to decision

K896122 · Product code: **KXO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k896122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intrauterine (KXO)
Date received	Oct 24, 1989
Decision date	Jan 19, 1990
Days to decision	87 days
Third-party review	No

APPLICANT

Company	**Spectramed, Inc.**
Location	Findley, MN, US
Contact	ROBERT L LEAVITT
510(k) history	13 submissions · 13 cleared · 1987-1990