FDA 510(k) Premarket Notification

CLEARED

K980090 ONECATH, L-CATH CATHETER SYSTEM, MODEL OC-(16-22 GA., 5CM-60CM)

Mar 24, 1998
74 days to decision

K980090 · Product code: **LJS** · General Hospital
Source: https://www.510kdatabase.net/k980090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Jan 9, 1998
Decision date	Mar 24, 1998
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Luther Medical Products, Inc.**
Location	Walker, MI, US
Contact	BARBARA C LUTHER
510(k) history	17 submissions · 16 cleared · 1980-1998