FDA 510(k) Premarket Notification

K930801 INTROPEEL

CLEARED

Sep 22, 1993
218 days to decision

K930801 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k930801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 16, 1993
Decision date	Sep 22, 1993
Days to decision	218 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Menlo Care, Inc.**
Location	Menlo Park, CA, US
Contact	THOM LAWSON
510(k) history	31 submissions · 25 cleared · 1986-1997