FDA 510(k) Premarket Notification

K820674 OPTICATH

CLEARED

Mar 25, 1982
14 days to decision

K820674 · Product code: **DQE** · Cardiovascular
Source: https://www.510kdatabase.net/k820674/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Oximeter, Fiber-optic (DQE)
Date received	Mar 11, 1982
Decision date	Mar 25, 1982
Days to decision	14 days
Third-party review	No

APPLICANT

Company	**Oximetrix, Inc.**
Location	Mchenry, IL, US
510(k) history	12 submissions · 12 cleared · 1976-1986