FDA 510(k) Premarket Notification

K914105 CATHWRITER(TM)

CLEARED

Feb 26, 1992
166 days to decision

K914105 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k914105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 13, 1991
Decision date	Feb 26, 1992
Days to decision	166 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Softheart, Inc.**
Location	South Burlington, VT, US
Contact	HENRY A GELLER
510(k) history	3 submissions · 3 cleared · 1992-1993