FDA 510(k) Premarket Notification

K973477 BIOSENSORS EMBOLECTOMY CATHETER

CLEARED

Sep 4, 1998
354 days to decision

K973477 · Product code: **DXE** · Cardiovascular
Source: https://www.510kdatabase.net/k973477/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Embolectomy (DXE)
Date received	Sep 15, 1997
Decision date	Sep 4, 1998
Days to decision	354 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sunscope Intl., Inc.**
Location	Westlake Village, CA, US
Contact	JOHN SHULZE
510(k) history	7 submissions · 7 cleared · 1991-2000