

K973477 BIOSENSORS EMBOLECTOMY CATHETERSep 4, 1998
354 days to decisionK973477 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973477/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026