FDA 510(k) Premarket Notification

K931403 SITERITE NEEDLE GUIDE (MODIFIED)

CLEARED

Jul 27, 1993
130 days to decision

K931403 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k931403/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 19, 1993
Decision date	Jul 27, 1993
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dymax Corp**
Location	Pittsburgh, PA, US
Contact	IRENE SKOLNICK
510(k) history	7 submissions · 7 cleared · 1985-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k931403/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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