FDA 510(k) Premarket Notification

K950634 CANDELA SHEATH SETS

CLEARED

Mar 1, 1995
16 days to decision

K950634 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k950634/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Feb 13, 1995
Decision date	Mar 1, 1995
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Candela Laser Corp.**
Location	Wayland, MA, US
Contact	THOMAS R VARRICCHIONE
510(k) history	43 submissions · 43 cleared · 1988-1996