FDA 510(k) Premarket Notification

K040067 CLIRPATH EXCIMER LASER CATHETER

CLEARED

Apr 27, 2004
104 days to decision

K040067 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k040067/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jan 14, 2004
Decision date	Apr 27, 2004
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spectranetics Corp.**
Location	Colorado Springs, CO, US
Contact	ADRIAN ELFE
510(k) history	24 submissions · 24 cleared · 1999-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k040067/ 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 7, 2026