FDA 510(k) Premarket Notification

K150709 ProTrack RF Anchor Wire

CLEARED

Jun 17, 2015
90 days to decision

K150709 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k150709/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Septostomy (DXF)
Date received	Mar 19, 2015
Decision date	Jun 17, 2015
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baylis Medical Company, Inc.**
Location	Mississauga, Ontario, CA
Contact	Meghal Khakhar
510(k) history	24 submissions · 24 cleared · 2012-2025