FDA 510(k) Premarket Notification

K051670 RF TUNNELER WIRE

CLEARED

Mar 30, 2006
281 days to decision

K051670 · Product code: **PDU** · Cardiovascular
Source: https://www.510kdatabase.net/k051670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jun 22, 2005
Decision date	Mar 30, 2006
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baylis Medical Co., Inc.**
Location	Mississauga, CA
Contact	MEGHAL KHAKHAR
510(k) history	28 submissions · 28 cleared · 1998-2013