FDA 510(k) Premarket Notification

K050073 MODIFICATION TO AMPHIRION DEEP 0.014 OTW PTA BALLOON CATHETER

CLEARED

Feb 11, 2005
30 days to decision

K050073 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k050073/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 12, 2005
Decision date	Feb 11, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invatec Innovative Technologies, S.R.L.**
Location	Plymouth, MN, US
Contact	MIKE WINEGAR
510(k) history	7 submissions · 7 cleared · 2005-2009