FDA 510(k) Premarket Notification

K042538 SAILOR PLUS PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER, MODEL SAEXXXXXXXXX

CLEARED

Nov 8, 2004
49 days to decision

K042538 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k042538/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 20, 2004
Decision date	Nov 8, 2004
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invatec Innovative Technologies**
Location	Plymouth, MN, US
Contact	MIKE WINEGAR
510(k) history	3 submissions · 3 cleared · 2004-2006