FDA 510(k) Premarket Notification

CLEARED

K092361 REEF HP 0.035 OTW PTA BALLOON DILATATION CATHETER

Oct 29, 2009
86 days to decision

K092361 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k092361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 4, 2009
Decision date	Oct 29, 2009
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invatec S.P.A.**
Location	Bethlehem, PA, US
Contact	JOHN CLAY
510(k) history	4 submissions · 3 cleared · 2009-2010