FDA 510(k) Premarket Notification

K120781 CELLO BALLOON GUIDE CATHETER (6F), 950 MM AND 1020 MM LENGTH

CLEARED

Aug 9, 2012
147 days to decision

K120781 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k120781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 15, 2012
Decision date	Aug 9, 2012
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fuji Systems Corp.**
Location	Mccordsville, IN, US
Contact	PAUL MASON
510(k) history	2 submissions · 2 cleared · 2005-2012