FDA 510(k) Premarket Notification

K123792 HORIZON XVU (FFR)

CLEARED

Aug 30, 2013
263 days to decision

K123792 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k123792/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 10, 2012
Decision date	Aug 30, 2013
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mennen Medical , Ltd.**
Location	Rehovot, IL
Contact	IFAT SHWARTS
510(k) history	21 submissions · 21 cleared · 2000-2015