

**K123792 HORIZON XVU (FFR)**Aug 30, 2013  
263 days to decisionK123792 · Product code: **DQX** · CardiovascularSource: <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	<b>Mennen Medical , Ltd.</b>
Location	Rehovot, IL
Contact	IFAT SHWARTS
510(k) history	21 submissions · 21 cleared · 2000-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123792/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026