

**K153599 Concert Medical Hands-Free Syringe (HFS)**Sep 1, 2016  
260 days to decisionK153599 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k153599/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Dec 16, 2015
Decision date	Sep 1, 2016
Days to decision	260 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Concert Medical, LLC</b>
Location	Ayer, MA, US
Contact	Timothy S Powers
510(k) history	3 submissions · 3 cleared · 2009-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153599/> 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 June 2, 2026