

**K153553 SiO2 Coated syringe 3 ml**May 17, 2016  
158 days to decisionK153553 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k153553/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 11, 2015
Decision date	May 17, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sio2 Medical Products</b>
Location	Auburn, AL, US
Contact	Sandra L True
510(k) history	1 submissions · 1 cleared · 2016-2016

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153553/> 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 3, 2026