

**K160190 Sunmed Control Syringes**Nov 10, 2016  
288 days to decisionK160190 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160190/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jan 27, 2016
Decision date	Nov 10, 2016
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sunny Medical Device (Shenzhen) Co., Ltd.</b>
Location	Irvine, CA, US
Contact	James Qi Zhang
510(k) history	6 submissions · 6 cleared · 2012-2020

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160190/> 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 28, 2026