

**K192657 Sterile High-pressure Angiographic Syringes for Single-use**Aug 7, 2020  
317 days to decisionK192657 · Product code: DXT · General Hospital  
Source: <https://www.510kdatabase.net/k192657/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Sep 25, 2019
Decision date	Aug 7, 2020
Days to decision	317 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shenzhen Boon Medical Supply Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Mingan Mu
510(k) history	3 submissions · 3 cleared · 2020-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192657/>. Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026