

**K211564 Sterile High-pressure Angiographic Syringes for Single-use**Oct 19, 2021  
152 days to decisionK211564 · Product code: DXT · General Hospital  
Source: <https://www.510kdatabase.net/k211564/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	May 20, 2021
Decision date	Oct 19, 2021
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211564/>. 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