

K241109 Single-use Sterile High-pressure Angiographic Syringes and AccessoriesAug 22, 2024
122 days to decisionK241109 · Product code: DXT · General Hospital
Source: <https://www.510kdatabase.net/k241109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Apr 22, 2024
Decision date	Aug 22, 2024
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Boon Medical Supply Co., Ltd.
Location	Shenzhen, CN
Contact	Shengyu Fan
510(k) history	3 submissions · 3 cleared · 2020-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241109/> 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 13, 2026