

K242143 Angiography InjectorDec 23, 2024
154 days to decisionK242143 · Product code: **DXT** · General Hospital
Source: <https://www.510kdatabase.net/k242143/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jul 22, 2024
Decision date	Dec 23, 2024
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Int Medical Instruments Co., Ltd.
Location	Rizhao, CN
Contact	Wei Zhang
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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