

K244038 High Pressure TubingSep 5, 2025
249 days to decisionK244038 · Product code: **DXT** · General Hospital
Source: <https://www.510kdatabase.net/k244038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Dec 30, 2024
Decision date	Sep 5, 2025
Days to decision	249 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	Zhang Wei
510(k) history	2 submissions · 2 cleared · 2024-2025

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