

K251788 Extension tubeMar 5, 2026
267 days to decisionK251788 · Product code: **DXT** · General Hospital
Source: <https://www.510kdatabase.net/k251788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 11, 2025
Decision date	Mar 5, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhuhai DR Medical Instruments Co., Ltd.
Location	Zhuhai, CN
Contact	Guanglong Zhang
510(k) history	2 submissions · 2 cleared · 2021-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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