FDA 510(k) Premarket Notification

K251788 Extension tube

CLEARED

Mar 5, 2026
267 days to decision

K251788 · 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