FDA 510(k) Premarket Notification

K253048 High Pressure Syringe

CLEARED

Apr 16, 2026
206 days to decision

K253048 · Product code: **DXT** · General Hospital
Source: https://www.510kdatabase.net/k253048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Sep 22, 2025
Decision date	Apr 16, 2026
Days to decision	206 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pressure Connecting Tube; Quick fill tube; Spike; Transfer Tube

APPLICANT

Company	**Shenzhen Maiwei Biotech Co., Ltd.**
Location	Shenzhen, CN
Contact	Woody Chen
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Chonconn Consulting Co., Ltd.**
Contact	Jie Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov