

K252652 Disposable Syringes with Accessories for Power Injectors (900103T)May 14, 2026
265 days to decisionK252652 · Product code: DXT · General Hospital
Source: <https://www.510kdatabase.net/k252652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 22, 2025
Decision date	May 14, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Disposable Syringes with Accessories for Power Injectors (900103H); Disposable Syringes with Accessories for Power Injectors (801800H); Disposable Syringes with Accessories for Power Injectors (800099T); Disposable Syringes with Accessories for Power Injectors (800099H); Disposable Syringes with Accessories for Power Injectors (800096T); Disposable Syringes with Accessories for Power Injectors (800096H); Disposable Syr

APPLICANT

Company	Fortis Biosolutions Company Limited
Location	Taoyuan City, TW
Contact	Sharon Au
510(k) history	1 submissions · 1 cleared · 2026-2026

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