

K243660 Monoject™ 1mL Tuberculin Syringe Luer-Lock Tip (1180100777)

Aug 22, 2025
268 days to decision

K243660 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k243660/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 27, 2024
Decision date	Aug 22, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Monoject™ 3mL Syringe, Luer-Lock Tip (1180300777); Monoject™ 6mL Syringe, Luer-Lock Tip (1180600777); Monoject™ 12mL Syringe, Luer-Lock Tip (1181200777); Monoject™ 20mL Syringe, Luer-Lock Tip (1182000777); Monoject™ 35mL Syringe, Luer-Lock Tip (1183500777); Monoject™ 60mL Syringe, Luer-Lock Tip (1186000777); Monoject™ 3mL Syringe, Luer-Lock Tip (8881513934); Monoject™ 6mL Syringe , Luer-Lock Tip (8881516937); Monojec

APPLICANT

Company	Cardinalhealth
Location	Mcgaw Park, IL, US
Contact	Kyle Hooper
Website	http://www.cardinalhealth.com
510(k) history	32 submissions · 32 cleared · 2003-2026

REGULATORY CONSULTANT

Consulting firm	Cardinal Health200, LLC
Contact	Kyle Hooper

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