FDA 510(k) Premarket Notification

K260208 Ultra-Fine™ SAFETY Insulin Syringe

CLEARED

Jul 13, 2026
171 days to decision

K260208 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k260208/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 23, 2026
Decision date	Jul 13, 2026
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**embecta Medical II, LLC**
Location	Parsippany, NJ, US
Contact	Ewelina Rog
510(k) history	1 submissions · 1 cleared · 2026-2026