

K093400 1ML UNITRACT INSULIN SYRINGE 27G X 1/2 AND 29G X 1/2

Apr 1, 2010
150 days to decision

K093400 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k093400/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Nov 2, 2009
Decision date	Apr 1, 2010
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unilife Medical Solutions Limited
Location	Sydney, Nsw, AU
Contact	MELISSA L DEHASS
510(k) history	3 submissions · 3 cleared · 2008-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k093400/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026