

K050800 NIKI T34 AND BODYGUARD T34 SYRINGE DRIVERSNov 23, 2005
238 days to decisionK050800 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k050800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Mar 30, 2005
Decision date	Nov 23, 2005
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Caesarea Medical Electronics , Ltd.
Location	Caesarea, IL
Contact	GALI TZURY
510(k) history	9 submissions · 9 cleared · 2003-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050800/> 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 25, 2026