

**K980181 TERUMO DISPOSABLE HYPODERMC SYRINGE**Apr 2, 1998  
72 days to decisionK980181 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k980181/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 20, 1998
Decision date	Apr 2, 1998
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Terumo Medical Corp.</b>
Location	Elkton, MD, US
Contact	KRISTINE WAGNER
510(k) history	143 submissions · 143 cleared · 1980-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980181/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026