

K970419 DAXOR MAX100 SYRINGE (MAX100)Dec 22, 1997
321 days to decisionK970419 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k970419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Feb 4, 1997
Decision date	Dec 22, 1997
Days to decision	321 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Daxor Corporation
Location	Oak Ridge, TN, US
Contact	RONALD H BALDRY
510(k) history	3 submissions · 3 cleared · 1997-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970419/> 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 May 26, 2026