

K964060 COPAXONE (COPOLYMER-1 FOR INJECTION) SELF-INJECTION ADMINISTRATION PACKAGE

Dec 24, 1996
76 days to decision

K964060 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k964060/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Oct 9, 1996
Decision date	Dec 24, 1996
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Travenol Laboratories (Israel) , Ltd.
Location	Kiriat Shemona, IL
Contact	HARRY LEINWAND
510(k) history	1 submissions · 1 cleared · 1996-1996

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Device record: <https://www.510kdatabase.net/k964060/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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