

K974171 COPAXONE (GLATIRAMER ACETATE FOR INJECTION) EZ-JECT FROM SHARED SOLUTIONSDec 19, 1997
44 days to decisionK974171 · Product code: **KZH** · General Hospital
Source: <https://www.510kdatabase.net/k974171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Syringe Needle (KZH)
Date received	Nov 5, 1997
Decision date	Dec 19, 1997
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Teva Medical, Ltd.
Location	Kulpsville, PA, US
Contact	HARRY LEINWAND
510(k) history	2 submissions · 2 cleared · 1997-1999

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