

**K970370 TSK STERIJEKT PREMIUM DISPOSABLE  
HYPODERMIC NEEDLE**Apr 10, 1997  
69 days to decisionK970370 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k970370/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 31, 1997
Decision date	Apr 10, 1997
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tsk Laboratory, Japan</b>
Location	Tochigi-Ken, JP
Contact	NORMAN S JOHNSON
510(k) history	3 submissions · 3 cleared · 1997-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970370/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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