

**K970547 ISOLYSER SDS SHARPS CONTAINER**Jul 18, 1997  
156 days to decisionK970547 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k970547/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 12, 1997
Decision date	Jul 18, 1997
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thantex Specialties, Inc.</b>
Location	Norcross, GA, US
Contact	TOM BONNER
510(k) history	21 submissions · 21 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970547/> 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 July 6, 2026