

**K963830 SHARPS CONTAINER MODEL# SC001**Feb 10, 1997  
139 days to decisionK963830 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k963830/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 24, 1996
Decision date	Feb 10, 1997
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Image Medical, Inc.</b>
Location	Jacksonville, FL, US
Contact	GARY BURDETTE
510(k) history	1 submissions · 1 cleared · 1997-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963830/> 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