

**K912053 OPEN HEART TRAY**Aug 26, 1991  
109 days to decisionK912053 · Product code: **FSM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k912053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Surgical, Instrument (FSM)
Date received	May 9, 1991
Decision date	Aug 26, 1991
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medical Device Inspection Co., Inc.</b>
Location	Great Neck, NY, US
Contact	ALAN P.SCHWARTZ
510(k) history	30 submissions · 26 cleared · 1990-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912053/> 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 June 30, 2026