

**K853604 ACE-KYLE DYE INJECTION NEEDLE P/N 14082**Nov 12, 1985  
76 days to decisionK853604 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k853604/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 28, 1985
Decision date	Nov 12, 1985
Days to decision	76 days
Third-party review	No

**APPLICANT**

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Company	<b>Today's Machining &amp; Design, Inc.</b>
Location	Mchenry, IL, US
Contact	MARK WILSON
510(k) history	4 submissions · 4 cleared · 1983-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853604/>; 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 May 23, 2026