

**K003348 E.N.S.I. RETRACTABLE SAFETY SYRINGE**Jan 12, 2001  
78 days to decisionK003348 · Product code: **MEG** · General Hospital  
Source: <https://www.510kdatabase.net/k003348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Oct 26, 2000
Decision date	Jan 12, 2001
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ensi-Med International Pty. , Ltd.</b>
Location	Seaford, Victoria, AU
Contact	NAP CURIE
510(k) history	1 submissions · 1 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003348/> 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 4, 2026