

**K010166 IMAGYN ISOSLEEVE / ISOSTAR NEEDLE SYSTEM**Dec 3, 2001  
319 days to decisionK010166 · Product code: **IWJ** · Radiology  
Source: <https://www.510kdatabase.net/k010166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Manual (IWJ)
Date received	Jan 18, 2001
Decision date	Dec 3, 2001
Days to decision	319 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imagyn Medical Technologies, Inc.</b>
Location	Richland, MI, US
Contact	JULIE POWELL
510(k) history	7 submissions · 6 cleared · 1998-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010166/> 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 19, 2026