

**K013620 MEDSTONE, UROPRO 2000, TOMOGRAPHIC OPTION**Jan 22, 2002  
78 days to decisionK013620 · Product code: **IZF** · Radiology  
Source: <https://www.510kdatabase.net/k013620/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomographic (IZF)
Date received	Nov 5, 2001
Decision date	Jan 22, 2002
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medstone Intl., Inc.</b>
Location	Irvine, CA, US
Contact	RON BERGESON
510(k) history	3 submissions · 3 cleared · 1991-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013620/> 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