

**K993574 OPART/PRODIGA, OPART/PROTENZA,  
OPART/PARAGON**Jan 18, 2000  
89 days to decisionK993574 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k993574/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 21, 1999
Decision date	Jan 18, 2000
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Toshiba America Mri, Inc.</b>
Location	South San Francisco, CA, US
Contact	KEN NEHMER
510(k) history	68 submissions · 68 cleared · 1990-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993574/>; 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