

**K984530 DRX NTX OR, OSTEOMARK NTX DIRECT RESPONSE**Aug 10, 1999  
232 days to decisionK984530 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k984530/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Dec 21, 1998
Decision date	Aug 10, 1999
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Metrika, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Erika B Ammirati
510(k) history	11 submissions · 11 cleared · 1999-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984530/> 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 June 28, 2026