

**K043336 OPTISTRAND, MODEL 1032S**Jan 21, 2005  
49 days to decisionK043336 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k043336/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Dec 3, 2004
Decision date	Jan 21, 2005
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ibt SA</b>
Location	Norcross, GA, US
Contact	RUTH FEICHT
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043336/> 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 18, 2026