

**K111979 RADIOACTIVE SEED LOCALIZATION NEEDLE**Oct 18, 2011  
98 days to decisionK111979 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k111979/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Jul 12, 2011
Decision date	Oct 18, 2011
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biocompatibles, Inc.</b>
Location	Oxford, CT, US
Contact	WAYNE RICHARDSON
Website	<a href="http://www.biocompatibles.com/">http://www.biocompatibles.com/</a>
510(k) history	3 submissions · 3 cleared · 2009-2011

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111979/>; 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 17, 2026