

**K140490 CIVA SHEET PD-103**Aug 29, 2014  
183 days to decisionK140490 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k140490/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Feb 27, 2014
Decision date	Aug 29, 2014
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Civatech Oncology, Inc.</b>
Location	Mebane, NC, US
Contact	BLIX WINSTON
510(k) history	3 submissions · 3 cleared · 2008-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140490/> 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 18, 2026