

**K082159 CIVASTRING PD-103**Sep 30, 2008  
61 days to decisionK082159 · Product code: **KXK** · Radiology  
Source: <https://www.510kdatabase.net/k082159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Jul 31, 2008
Decision date	Sep 30, 2008
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Civatech Oncology, Inc.</b>
Location	Mebane, NC, US
Contact	LOIS V SMART
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/k082159/> 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