

**K110590 INTRABEAM NEEDLE APPLICATOR**Apr 13, 2012  
408 days to decisionK110590 · Product code: **JAD** · Radiology  
Source: <https://www.510kdatabase.net/k110590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Mar 2, 2011
Decision date	Apr 13, 2012
Days to decision	408 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carl Zeiss Surgical GmbH</b>
Location	North Attleboro, MA, US
Contact	JUDITH A BRIMACOMBE, MA
510(k) history	4 submissions · 4 cleared · 2005-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110590/> 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