

**K132092 ESTEYA**Sep 26, 2013  
83 days to decisionK132092 · Product code: **JAD** · Radiology  
Source: <https://www.510kdatabase.net/k132092/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Jul 5, 2013
Decision date	Sep 26, 2013
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nucletron B.V.</b>
Location	Rice Lake, WI, US
Contact	LU ANNE JOHNSON
510(k) history	11 submissions · 11 cleared · 2013-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k132092/> 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 26, 2026