

**K182012 ADVIA Centaur Calcitonin (CALCT) assay**Dec 21, 2018  
147 days to decisionK182012 · Product code: **JKR** · Chemistry  
Source: <https://www.510kdatabase.net/k182012/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Calcitonin (JKR)
Date received	Jul 27, 2018
Decision date	Dec 21, 2018
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis-Shield Diagnostics Limited</b>
Location	Dundee, GB
Contact	Claire Dora
510(k) history	4 submissions · 4 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182012/> 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 20, 2026