

**K182218 FerriSmart Analysis System**Nov 30, 2018  
107 days to decisionK182218 · Product code: **PCS** · Radiology  
Source: <https://www.510kdatabase.net/k182218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liver Iron Concentration Imaging Companion Diagnostic For Deferasirox (PCS)
Date received	Aug 15, 2018
Decision date	Nov 30, 2018
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Resonance Health Analysis Services Pty, Ltd.</b>
Location	Irvine, CA, US
Contact	Celine Royet
510(k) history	7 submissions · 6 cleared · 2011-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182218/> 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