

K213776 LiverSmartDec 29, 2021
27 days to decisionK213776 · Product code: **PCS** · Radiology
Source: <https://www.510kdatabase.net/k213776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Liver Iron Concentration Imaging Companion Diagnostic For Deferasirox (PCS)
Date received	Dec 2, 2021
Decision date	Dec 29, 2021
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Resonance Health Analysis Services Pty, Ltd.
Location	Irvine, CA, US
Contact	Mitchell Wells
510(k) history	7 submissions · 6 cleared · 2011-2023

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