

**K211279 Volpara Imaging Software**Jul 27, 2021  
91 days to decisionK211279 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k211279/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 27, 2021
Decision date	Jul 27, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Volpara Health Technologies Limited</b>
Location	Wellington, NZ
Contact	Ralph Highnam
510(k) history	2 submissions · 2 cleared · 2018-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211279/> 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