

**K193173 CareView 1800Le**Dec 13, 2019  
25 days to decisionK193173 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k193173/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 18, 2019
Decision date	Dec 13, 2019
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Careray Digital Medical System Co., Ltd.</b>
Location	Campbell, CA, US
Contact	Leilei Li
510(k) history	10 submissions · 10 cleared · 2015-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193173/> 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 27, 2026