

**K193498 Infinitt RT PACS**Feb 13, 2020  
58 days to decisionK193498 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k193498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 17, 2019
Decision date	Feb 13, 2020
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infinitt Healthcare Co., Ltd.</b>
Location	Seoul, KR
Contact	Sang Wook Cho
510(k) history	4 submissions · 4 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193498/> 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