

**K212470 iRAD**Oct 20, 2021  
75 days to decisionK212470 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k212470/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received         | Aug 6, 2021                                  |
| Decision date         | Oct 20, 2021                                 |
| Days to decision      | 75 days                                      |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Claritas Healthtech Pte, Ltd.</b>  |
| Location       | Singapore, SG                         |
| Contact        | Devika Dutt                           |
| 510(k) history | 3 submissions · 3 cleared · 2021-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212470/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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