

**K162555 EVS 4343, EVS 4343G**Dec 21, 2016  
99 days to decisionK162555 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k162555/>**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         | Sep 13, 2016   |
| Decision date         | Dec 21, 2016   |
| Days to decision      | 99 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>DRTECH Corporation</b>               |
| Location       | Seongam-Si, KR                          |
| Contact        | CHOUL-WOO SHIN                          |
| 510(k) history | 25 submissions · 25 cleared · 2015-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162555/> 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 16, 2026