

**K152767 OTC12D AUTO RADIOGRAPHIC SYSTEM**Dec 14, 2015  
81 days to decisionK152767 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k152767/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Abbreviated                        |
| Device classification | System, X-ray, Stationary (KPR)    |
| Date received         | Sep 24, 2015                       |
| Decision date         | Dec 14, 2015                       |
| Days to decision      | 81 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Del Medical, Inc.</b>              |
| Location       | Naples, FL, US                        |
| Contact        | JOHN HARTZELL                         |
| 510(k) history | 4 submissions · 4 cleared · 2014-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152767/> 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