

**K122454 FUJIFILM DUAL ENERGY SUBTRACTION (DES)  
SOFTWARE OPTION**

Nov 20, 2012  
99 days to decision

K122454 · Product code: **KPR** · Radiology  
Source: <https://www.510kdatabase.net/k122454/>

**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Stationary (KPR)    |
| Date received         | Aug 13, 2012                       |
| Decision date         | Nov 20, 2012                       |
| Days to decision      | 99 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Fujifilm Medical System U.S.A., Inc.</b> |
| Location       | Stamford, CT, US                            |
| Contact        | DEBBIE PEACOCK                              |
| 510(k) history | 71 submissions · 71 cleared · 1988-2017     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k122454/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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