

**K171755 CS-series-FP with MX CFP 3131 or MX CFP 2222
Option Radiographic/Fluoroscopy System**Feb 9, 2018
241 days to decisionK171755 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k171755/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Jun 13, 2017 |
| Decision date | Feb 9, 2018 |
| Days to decision | 241 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Omega Medical Imaging, LLC |
| Location | Sanford, FL, US |
| Contact | John Newman |
| 510(k) history | 7 submissions · 7 cleared · 2012-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171755/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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