

K132413 MZ1000Aug 29, 2013
27 days to decisionK132413 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k132413/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Aug 2, 2013 |
| Decision date | Aug 29, 2013 |
| Days to decision | 27 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Care Fusion |
| Location | Waukegan, IL, US |
| Contact | MICHELLE J BADAL, RAC |
| 510(k) history | 34 submissions · 29 cleared · 2010-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132413/> Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026