

K193088 MaxZero Extension Sets with Needle-Free Connector(s)Oct 23, 2020
352 days to decisionK193088 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k193088/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Nov 6, 2019 |
| Decision date | Oct 23, 2020 |
| Days to decision | 352 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Carefusion, Inc. |
| Location | Vernon Hills, IL, US |
| Contact | Viviana Lai |
| 510(k) history | 3 submissions · 3 cleared · 2016-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193088/> 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 28, 2026