

**K234129 Ecomed Disposable Administration Sets**Sep 20, 2024  
267 days to decisionK234129 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k234129/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received         | Dec 28, 2023                             |
| Decision date         | Sep 20, 2024                             |
| Days to decision      | 267 days                                 |
| Third-party review    | No                                       |
| Combination product   | No                                       |
| PCCP authorized       | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ecomed Solutions, LLC</b>          |
| Location       | Mundelein, IL, US                     |
| Contact        | David Yurek                           |
| 510(k) history | 2 submissions · 2 cleared · 2017-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234129/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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