

**K210461 End Cap**Sep 14, 2021  
210 days to decisionK210461 · Product code: **MSD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210461/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Catheter, Hemodialysis, Implanted (MSD) |
| Date received         | Feb 16, 2021                            |
| Decision date         | Sep 14, 2021                            |
| Days to decision      | 210 days                                |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Medical Components Inc (Medcomp)</b> |
| Location       | Harleysville, PA, US                    |
| Contact        | Patrick McDonald                        |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210461/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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