

**K190487 InPen Dose Calculator**Feb 18, 2020  
355 days to decisionK190487 · Product code: **NDC** · Chemistry  
Source: <https://www.510kdatabase.net/k190487/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Calculator, Drug Dose (NDC)        |
| Date received         | Feb 28, 2019                       |
| Decision date         | Feb 18, 2020                       |
| Days to decision      | 355 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Companion Medical, Inc.</b>        |
| Location       | San Diego, CA, US                     |
| Contact        | Jasper Benke                          |
| 510(k) history | 5 submissions · 5 cleared · 2016-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190487/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026