

**K201337 InPen System**Jun 18, 2020  
29 days to decisionK201337 · Product code: **NDC** · General Hospital  
Source: <https://www.510kdatabase.net/k201337/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calculator, Drug Dose (NDC)
Date received	May 20, 2020
Decision date	Jun 18, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201337/> 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