

**K232224 iLet® Dosing Decision Software**Sep 22, 2023  
57 days to decisionK232224 · Product code: **QJI** · Chemistry  
Source: <https://www.510kdatabase.net/k232224/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Interoperable Automated Glycemic Controller (QJI) |
| Date received         | Jul 27, 2023                                      |
| Decision date         | Sep 22, 2023                                      |
| Days to decision      | 57 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Beta Bionics, Inc.</b>   |
| Location       | Concord, MA, US   |
| Contact        | Liz Cooper  |
| Website        | <a href="https://www.betabionics.com">https://www.betabionics.com</a> |
| 510(k) history | 6 submissions · 6 cleared · 2023-2026                                 |

Beta Bionics, Inc. develops automated insulin delivery systems for type 1 diabetes management. The company is dedicated to simplifying diabetes care through innovative technology. Beta Bionics operates with a manufacturing facility in Concord, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2023. All submissions focus on Chemistry devices. The latest clearance occurred in 2026, confirming the company remains actively engaged in regulatory submissions. Beta Bionics specializes in Chemistry devices, including the iLet B...

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