

K220916 iLet® Dosing Decision SoftwareMay 19, 2023
415 days to decisionK220916 · Product code: **QJI** · Chemistry
Source: <https://www.510kdatabase.net/k220916/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Interoperable Automated Glycemic Controller (QJI) |
| Date received | Mar 30, 2022 |
| Decision date | May 19, 2023 |
| Days to decision | 415 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Beta Bionics, Inc. |
| Location | Concord, MA, US |
| Contact | Vikram Verma |
| Website | https://www.betabionics.com |
| 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...
