

K230545 Inessa SystemDec 20, 2023
295 days to decisionK230545 · Product code: **QFG** · Chemistry
Source: <https://www.510kdatabase.net/k230545/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Alternate Controller Enabled Insulin Infusion Pump (QFG) |
| Date received | Feb 28, 2023 |
| Decision date | Dec 20, 2023 |
| Days to decision | 295 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Triple Jump Israel , Ltd. |
| Location | Yokneam Lllit, IL |
| Contact | Liron Hadar |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------------|
| Consulting firm | Hogan Lovells US LLP |
| Contact | Janice Hogan |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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