

K201880 MultiSure GK Link Blood Glucose and Ketone Monitoring SystemOct 15, 2021
465 days to decisionK201880 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k201880/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received | Jul 7, 2020 |
| Decision date | Oct 15, 2021 |
| Days to decision | 465 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Apex BioTechnology Corp. |
| Location | Plymouth, MN, US |
| Contact | Lisu Liu |
| 510(k) history | 35 submissions · 35 cleared · 2001-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201880/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026