FDA 510(k) Premarket Notification

# K223722 MIO Blood Glucose Monitoring System

**CLEARED**

Jun 28, 2023
198 days to decision

K223722 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k223722/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received | Dec 12, 2022 |
| Decision date | Jun 28, 2023 |
| Days to decision | 198 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Mio Labs, Inc.** |
| Location | Santa Clara, CA, US |
| Contact | Mark Qian |
| 510(k) history | 1 submissions · 1 cleared · 2023-2023 |