FDA 510(k) Premarket Notification

CLEARED

K213061 SuperCheck Pro Blood Glucose Monitoring System

Oct 7, 2022
380 days to decision

K213061 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k213061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Sep 22, 2021
Decision date	Oct 7, 2022
Days to decision	380 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ok Biotech Co., Ltd.**
Location	Hsin-Chu City, TW
Contact	Laurie Liu
510(k) history	9 submissions · 9 cleared · 2007-2022

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k213061/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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