

K212248 GlucoLeader Enhance 2 Blood Glucose Monitoring System

Aug 29, 2022
406 days to decision

K212248 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k212248/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jul 19, 2021
Decision date	Aug 29, 2022
Days to decision	406 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hmd Biomedical, Inc.
Location	Ocean, NJ, US
Contact	Chin-Hsiung Hsu
510(k) history	10 submissions · 10 cleared · 2003-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k212248/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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