

K182428 GlucoLeader Enhance Blood Glucose Monitoring System

May 8, 2019
244 days to decisionK182428 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k182428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Sep 6, 2018
Decision date	May 8, 2019
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hmd Biomedical, Inc.
Location	Ocean, NJ, US
Contact	Jen Ke-Min
510(k) history	10 submissions · 10 cleared · 2003-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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