

K113307 GL GOODLIFE SERIES BLOOD GLUCOSE MONITORING SYSTMEM

Jul 27, 2012
262 days to decision

K113307 · Product code: LFR · Chemistry
Source: <https://www.510kdatabase.net/k113307/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Nov 8, 2011
Decision date	Jul 27, 2012
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k113307/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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