FDA 510(k) Premarket Notification

K122688 NOVA MAX MINI BLOOD GLUCOSE AND B-KETONE MONITOR

CLEARED

Apr 4, 2013
212 days to decision

K122688 · Product code: **LFR** · Chemistry
Source: https://www.510kdatabase.net/k122688/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Sep 4, 2012
Decision date	Apr 4, 2013
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nova Biomedical Corporation**
Location	Waltham, MA, US
Contact	PAUL W MACDONALD
510(k) history	40 submissions · 40 cleared · 2011-2026