

K160282 SD LipidoCare Professional System, SD LipidoCare Home System, SD LipidoCare BT Professional System, SD LipidoCare BT Home System

Oct 17, 2017
623 days to decision

K160282 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k160282/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Feb 2, 2016
Decision date	Oct 17, 2017
Days to decision	623 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sd Biosensor
Location	Great Neck, NY, US
Contact	Sunok Go
510(k) history	4 submissions · 4 cleared · 2014-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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