

K191038 On Call Express Voice Blood Glucose Monitoring System

Jun 12, 2019
55 days to decisionK191038 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k191038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Apr 18, 2019
Decision date	Jun 12, 2019
Days to decision	55 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	ACON Laboratories, Inc.
Location	San Diego, CA, US
Contact	Qiyi Xie
Website	http://www.aconlabs.com/
510(k) history	85 submissions · 85 cleared · 1998-2025

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...