

K222888 BlueStar CGM insulin dose calculatorAug 11, 2023
322 days to decisionK222888 · Product code: **QRX** · Chemistry
Source: <https://www.510kdatabase.net/k222888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Glucose Monitor Informed Insulin Dose Calculator (QRX)
Date received	Sep 23, 2022
Decision date	Aug 11, 2023
Days to decision	322 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Welldoc, Inc.
Location	Baltimore, MD, US
Contact	Ian Cadieux
510(k) history	11 submissions · 11 cleared · 2010-2023

CLINICAL EVIDENCE - NCT05229445**A Continuous Glucose Monitor Based Insulin Bolus Calculator**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	27 patients (actual)
Study sites	1 site
Condition studied	Diabetes Mellitus, Type 2; Diabetes Mellitus, Type 1
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 28, 2022
Sponsor	Welldoc (Industry)

Primary outcome

time in range

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05229445510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222888/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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