

**K203434 BlueStar Rx**Sep 8, 2021  
289 days to decisionK203434 · Product code: **NDC** · Chemistry  
Source: <https://www.510kdatabase.net/k203434/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Nov 23, 2020
Decision date	Sep 8, 2021
Days to decision	289 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Welldoc, Inc.</b>
Location	Baltimore, MD, US
Contact	Sabyasachi Roy
510(k) history	11 submissions · 11 cleared · 2010-2023

**CLINICAL EVIDENCE - NCT02813343**

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**Evaluate the Value of Telehomecare for Diabetes**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	221 patients (actual)
Study sites	1 site
Condition studied	Type 2 Diabetes
Primary purpose	Supportive_care
Study type	Interventional
Study design	Crossover
Masking	Single blind
Completion date	Jun 1, 2017
Sponsor	Women&apos;s College Hospital (Other)

**Primary outcome**

Glucose control (HbA1c levels)

**Secondary outcome**

Patient reported health outcomes and utilization - ER visit

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT02813343](https://clinicaltrials.gov/study/NCT02813343)