

K231679 CONTOUR® PLUS BLUE Blood Glucose Monitoring System

Feb 23, 2024
259 days to decisionK231679 · Product code: NBW · Chemistry
Source: <https://www.510kdatabase.net/k231679/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jun 9, 2023
Decision date	Feb 23, 2024
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ascensia Diabetes Care
Location	Mishawaka, IN, US
Contact	Shahrir Alam
510(k) history	5 submissions · 5 cleared · 2016-2024

CLINICAL EVIDENCE - NCT04008836

User Performance of the Thunder Plus BGMS

Status	Completed
Enrollment	384 patients (actual)
Study sites	1 site
Condition studied	Diabetes Mellitus
Primary purpose	Supportive_care
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 31, 2019
Sponsor	Ascensia Diabetes Care (Industry)

Primary outcome

Number of Participants With Accurate BGMS Fingerstick Results

Secondary outcome

Number of Participants With Accurate BGMS Palm (AST) Results.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04008836