FDA 510(k) Premarket Notification

CLEARED

K193475 OneTouch Verio Reflect Blood Glucose Monitoring System

Feb 14, 2020
60 days to decision

K193475 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k193475/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 16, 2019
Decision date	Feb 14, 2020
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifescan Europe GmbH**
Location	Zug, CH
Contact	Niki Skelly
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Lifescan Scotland, Ltd.**
Contact	Niki Skelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03851549

A User Performance and System Use Evaluation of a New Blood Glucose Monitoring System (BGMS)

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	360 patients (estimated)
Study sites	4 sites
Condition studied	Diabetes Mellitus
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 19, 2019
Sponsor	LifeScan Scotland Ltd (Industry)

Primary outcome

User Performance (UP)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03851549