CLEARED

K220633 MICROLET NEXT lancing device, MICROLET Lancet

Jun 3, 2022
91 days to decision

K220633 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220633/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Mar 4, 2022
Decision date	Jun 3, 2022
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ascensia Diabetes Care U.S., Inc.**
Location	Mishawaka, IN, US
Contact	Sangram Yadav
510(k) history	7 submissions · 7 cleared · 2016-2025

CLINICAL EVIDENCE - NCT02606838

Evaluation of an Ascensia Lancing System

Status	Completed
Enrollment	119 patients (actual)
Study sites	1 site
Condition studied	Diabetes
Primary purpose	Supportive_care
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 1, 2015
Sponsor	Ascensia Diabetes Care (Industry)

Primary outcome

Number of Subjects With Numeric Meter Results When Users Obtain Fingerstick Capillary Blood Using the Styx Lancing Device (28 Gauge Lancets)

Secondary outcome

Number of Subjects With Numeric Meter Results When Users Obtain Alternate Site (AST) Palm Blood Using the Styx Lancing Device (28 Gauge Lancets)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02606838