FDA 510(k) Premarket Notification

K190898 Sight OLO

CLEARED

Nov 1, 2019
210 days to decision

K190898 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k190898/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Apr 5, 2019
Decision date	Nov 1, 2019
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sight Diagnostics , Ltd.**
Location	Tel Aviv, IL
Contact	Sarah Levy
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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

CLINICAL EVIDENCE - NCT03595501

Analytical and Clinical Performance Testing Plan

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	679 patients (actual)
Study sites	1 site
Condition studied	Hematology; Hematologic Test
Study type	Observational
Completion date	Aug 25, 2019
Sponsor	Sight Diagnostics (Industry)

Primary outcome

Reproducibility of CBC parameters provided by the OLO device

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03595501