FDA 510(k) Premarket Notification

K211840 Sight OLO

CLEARED

May 9, 2022
329 days to decision

K211840 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k211840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 14, 2021
Decision date	May 9, 2022
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**S.D. Sight Diagnostics , Ltd.**
Location	Tel Aviv, IL
Contact	Sarah Levy
510(k) history	1 submissions · 1 cleared · 2022-2022

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