FDA 510(k) Premarket Notification

K222148 HemoScreen Hematology Analyzer

CLEARED

Aug 16, 2023
392 days to decision

K222148 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k222148/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jul 20, 2022
Decision date	Aug 16, 2023
Days to decision	392 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pixcell Medical Technologies, Ltd.**
Location	Pob 113 Yoknaem Ilit, IL
Contact	Yaara Ben Yosef
510(k) history	2 submissions · 2 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	**Ammirati Regulatory Consulting**
Contact	Erika Ammirati

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