

K181475 DxH 520 Hematology InstrumentMar 1, 2019
270 days to decisionK181475 · Product code: **GKZ** · Hematology
Source: <https://www.510kdatabase.net/k181475/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Counter, Differential Cell (GKZ)
Date received	Jun 4, 2018
Decision date	Mar 1, 2019
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter
Location	Miami, FL, US
Contact	Samy Puccio
Website	http://www.beckmancoulter.com/
510(k) history	8 submissions · 6 cleared · 2017-2024

Beckman Coulter is a global diagnostics company specializing in clinical laboratory instruments and assays. The company operates with a manufacturing facility in Miami, US, and provides comprehensive diagnostic solutions across immunology, hematology, chemistry, and microbiology disciplines. The company has received FDA 510(k) clearances from total submissions since 2017. Immunology devices, particularly flow cytometers and related panels, represent a dominant category in the company's cleared portfolio. The latest FDA 510(k) clearance was granted in 2024, reflecting cont...
