FDA 510(k) Premarket Notification

K102778 CELLAVISION DM1200 WITH THE BODY FLUID APPLICTION

CLEARED

Sep 16, 2011
357 days to decision

K102778 · Product code: **JOY** · Hematology
Source: https://www.510kdatabase.net/k102778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Sep 24, 2010
Decision date	Sep 16, 2011
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**CellaVision AB**
Location	Minneapolis,, MN, US
Contact	CONSTANCE G BUNDY
510(k) history	7 submissions · 7 cleared · 2001-2020