

K201814 BD FACSLyric Flow Cytometer (3-1, 4-2, 4-2-2, 4-3-3 and 4-3-5 optical configurations), BD FACSDuet Sample Preparation System, BD FACS Universal Loader, BD FACSuite Clinical software, BD Multitest 6-Color Assay Modules, BD Multitest 4-Color Assay Modules, BD FACSFlow Sheath Fluid, BD CS&T Beads, BD FC Beads 7-Color Kit

Sep 28, 2020
89 days to decision

K201814 · Product code: OYE · Immunology
Source: <https://www.510kdatabase.net/k201814/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flow Cytometric Reagents And Accessories. (OYE)
Date received	Jul 1, 2020
Decision date	Sep 28, 2020
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Becton, Dickinson and Company
Location	Franklin Lakes, NJ, US
Contact	Niya Su
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagement...