Section 1.3.
510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is _____.

Submitter Information (21 CFR 807.92(a)(1))

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Device Name / Classification (21 CFR 807.92(a)(2))

Name: BD™ HLA-B27 system

Classification: unclassified

Substantially Equivalent/Predicate Device (21 CFR 807.92(a)(3))

The BD HLA-B27 system is substantially equivalent to the BD HLA-B27 system as cleared under BK940015, and BK050062. Both in vitro diagnostic assays have a similar intended use, measure the same sample types and have similar performance characteristics.

Device Description (21 CFR 807.92(a)(4))

The BD HLA-B27 system is a flow cytometric in vitro diagnostic assay used to detect HLA-B27 antigen expression in erythrocyte-lysed whole blood.

Intended Use (21 CFR 807.92(a)(5))

The BD HLA-B27 system is a qualitative two-color direct immunofluorescence method for the rapid detection of HLA-B27 antigen expression in erythrocyte-lysed whole blood (LWB) using the BD FACSCanto™ flow cytometer, or the BD FACSCalibur™, BD FACSort™, or BD FACScan™ flow cytometers.

Technological Characteristics (21 CFR 807.92(a)(6))

The following summary table describes the similarities and differences between the BD HLA-B27 system, cleared under BK050062, and the BD HLA-B27 system on the BD FACSCanto platform.

Characteristic	BD HLA-B27 system BK940015, and BK050062. FACSCanto instrument K041074 (predicates)	BD HLA-B27 system for the BD FACSCanto (test)
Intended Use	The BD HLA-B27 system is a qualitative two-color direct immunofluorescence method for the rapid testing of HLA-B27 antigen expression in erythrocyte-lysed whole blood (LWB) using the BD FACSCalibur™, BD FACSort™, or BD FACScan™ flow cytometers.	The BD HLA-B27 system is a qualitative two-color direct immunofluorescence method for the rapid detection of HLA-B27 antigen expression in erythrocyte-lysed whole blood (LWB) using the BD FACSCanto™ flow cytometer, or the BD FACSCalibur™, BD FACSort™, or BD FACScan™ flow cytometers.
Device Classification and Product Code	Class II Product Code: GKZ CFR Section 864.5220	Same
Reagent classification	unclassified	Same
Reagent	BD HLA-B27	Same
Sample Type	Whole blood preserved with EDTA, heparin, or ACD-Solution A	Same
Instrument electronics	Analog	Digital
Software	BD HLA-B27 software (BK940015 and BK050062)	BD FACSCanto software
Computer	HP Consort 30, 32	PC
Results	HLA-B27 positive or HLA-B27 negative	HLA-B27 positive or HLA-B27 negative Labeling also contains a representative profile of cross-reactivity with a recommended grey zone.

Performance Data (21 CFR 807.92(b)(1)and (2))

Equivalence for the candidate product has been demonstrated through method comparison, precision/reproducibility, and stability.

A) Results of Method comparison:

Predicate method/Instrument	Agreement	Disagreement	Overall Agreement	Results calculated based on 95% lower confidence Interval	Candidate
BD FACSCalibur	100%	0%	100%	99%	BD FACSCanto

B) Summary of System Precision:

Precision parameter	Sample	95% UCL** standard deviation (LMF)	Standard Deviation (LMF)
Within Run	n = 10*	0.82	0.67
Total	n = 10*	1.77	1.52

* 5 HLA-B27–positive and 5 HLA-B27–negative samples were evaluated.
** Upper Confidence Limit

C) Results of Sample Stability: *Age of Blood* (48 hours)

Tube Type	n	Mean difference in LMF with 95% CI (LMF)	Results (±5 LMF channels T^0)
ACD-A	87	-2.93 (-3.4 , -2.46)	PASS
Heparin	50	-1.09 (-1.63 , -0.55)	PASS
EDTA	37	-1.62 (-2.63 , -0.61)	PASS

D) Results of Sample Stability: ***Age of Stain (24 hours)***

Tube Type	n	Mean difference in LMF with 95% CI (LMF)	Results (±4 LMF channels T°)
ACD-A	87	-0.84 (-1.03 , -0.66)	PASS
Heparin	50	-0.84 (-1.02 , -0.66)	PASS
EDTA	37	-0.30 (-.30 , -0.83)	PASS

Conclusions from Performance Data (21 CFR 807.92(b)(3))

The BD HLA-B27 system, analyzed on the BD FACSCanto flow cytometer, demonstrates substantial equivalence to the predicate method.