

Attachment D  
*Summary of Safety & Effectiveness*

JUN - 7 1996

K961623

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

Submitter: Becton Dickinson Immunocytometry Systems  
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Summary date: April 24, 1996

Name of Device and Classification (21 CFR 807.92(a)(2))

Name: CaliBRITE™ 3 Color and FACSCComp™

Classification: Accessory to a Class II Device

Predicate Device (21 CFR 807.92(a)(3))

CaliBRITE™ 3 Color and FACSCComp™ is substantially equivalent to CaliBRITE™ Beads with AutoCOMP™ (K 925274), cleared to market in September, 1994.

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

Becton Dickinson CaliBRITE 3 Color and FACSCComp are intended for use on the Becton Dickinson flow cytometers FACScan™ or FACSort™ or FACSCalibur™. FACSCComp Software and CaliBRITE 3 Color Beads are used to optimally adjust instrument settings, to monitor the sensitivity, and to set the compensation of flow cytometers for spectral overlap of fluorescent dyes. FACSCComp Software and CaliBRITE 3 Color Beads are used to set up and verify the separation of system noise from forward and side scatter and to set fluorescence compensation on flow cytometers with three FL channels. FACSCComp Software and CaliBRITE 3 Color Beads are used for setting the photomultiplier tube (PMT) voltages, setting the fluorescence compensation, and checking instrument sensitivity on flow cytometers. This product is recommended for instrument set up prior to running Becton Dickinson software applications for flow cytometers. CaliBRITE 3 Color will be provided as a Kit, comprising unstained, FITC, PE and PerCP beads. CaliBRITE PerCP beads will also be provided as a separate product, to be used with CaliBRITE Kits having unstained FITC and PE beads only.

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

For flow cytometer set up and monitoring of instrument performance.

Indications for Use

The procedure employs a Becton Dickinson flow cytometer and recommended computer hardware and software.

Clinical Utility

Flow Cytometry has been found useful in monitoring some forms of immune disease.

Comparison to Predicate Device (21 CFR 807.92(a)(6))

CaliBRITE 3 Color with FACSComp is substantially equivalent to CaliBRITE Beads with AutoCOMP, (K925274). The product is composed of a bead kit with three components identical to that of the predicate, and one new bead, conjugated with PerCP, to check sensitivity of the FL3 channel.

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

Performance of this product was established by testing at Becton Dickinson Immunocytometry Systems laboratories in San Jose, California.

Several studies were performed:

- Stability was measured

Storage stability was determined to be 8 months under the conditions of use.

Once diluted, the three-bead preparation is stable for 1 hour after dilution.

- Reproducibility was measured

Within instrument over 30 days

Between lot

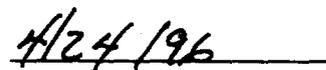
Reproducibility was found to be within that for the predicate device.

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

The results of the design verification studies demonstrate that the device is as safe and effective as the predicate device.



Anna Longwell, Esq.  
Director, Regulatory Affairs – Corporate



Date