

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE**

A. 510(k) Number:

K030192

B. Instrument Name:

Bio View Ltd. Duet™ System

C. System Descriptions:

1. Modes of Operation:

The Duet System is an automated scanning microscope and image analysis system. It is intended for in-vitro diagnosis use as an aiding tool to the pathologist in the detection, classification and counting of cells of interest based on particular color, intensity, size, pattern, and shape. There are two modes of operation:

- Automatic scanning: provides a gallery of targets that the system captures for all identified cells.
- Manual scanning: provides interactive control over the microscope. This enables a user-controlled scan of any slide under either bright field or fluorescent illumination.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

3. Sample Identification:

Individual specimen slide case details are entered in a Slide Configuration dialog box where case details and a name are assigned to a slide. The scan process (fluorescent or brightfield), mode of scanning (automatic or interactive), scan task, and scan program (coordinates) details are entered.

4. Specimen Sampling and Handling:

Standardized cell preparations on peripheral blood and bone marrow specimens are applied to microscope slides.

5. Assay Types:

Morphological staining, Immunohistochemistry, and Fluorescent *in situ* Hybridization (FISH).

6. Reaction Types:

N/A

7. Calibration:

Calibration is recommended at least once every 6 months by Bio View service personnel.

8. Quality Control:

N/A

D. Other Supportive Performance Characteristics Data Not Covered In The “L. Performance Characteristics” Section Of The SE Decision Summary.

Performance characteristics of the Duet System were determined by three studies:

1. Comparison of the routine manual method and the Duet method: NCCLS-EP9, *Method Comparison and Bias Estimation Using Patient Samples*; *Approved Guideline* was used to determine accuracy. A set of 41 slides of hematopoietic cells (17 bone marrow and 24 peripheral blood) were examined by the routine manual method by two independent experts and by analysis using the Duet System. Scatter plots for 1. means of test duplicates versus means of comparative duplicates; 2. individual tests versus means of comparative duplicates; 3. means of replicate deltas versus mean comparative method; and 4. bias plot individual results versus mean comparative method. The correlation coefficient was 0.9977 with a slope of 0.9983 and an intercept of 0.3482. The study demonstrated that a confidence level of 95%, the difference between the results reported by manual scoring and those obtained by the Duet System are smaller than 1/3%

2. Image quality: adequacy for analysis of images: The study had two parts:

A. Evaluation of the images: Two experts rated the images produced by the Duet System for image quality, clinical adequacy, loss of data, image alteration, and safety concerns. A set of 26 slides was used “from various origins.” On each slide images of 30 cells were compared by the above parameters. The study showed that for most parameters the average percentage of adequate cells was the maximal 100%. It was concluded that the images obtained by the Duet system are adequate for clinical analysis.

B. Matching between cells' images: The study examined the correlation between brightfield and fluorescent illumination of scans of the same slide. The same slide was scanned twice on the same Duet system, once under brightfield illumination and once under fluorescent illumination. The test was designed to examine the correlation between the two tests. A set of 5 slides were tested with 30 cells examined on each slide to study the correlation between the two tests. It was determined that the study demonstrated complete correlation of images between the readings by the two scanning modes.

3. Evaluation of precision performance within a system and across systems: NCCLS-EP5, *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline* was used to determine precision. A set of six slides with each slides analyzed on three different systems and three times on one of these systems. Two operators performed the study over a period of 17 days. One of the limitations is that FISH slides bleach after a few minutes under fluorescent illumination. Therefore the practical number of tests on the same slide is 5-6 times. Intra-system precision showed no clinically significant differences with a CV of 5.5%. ANOVA was used to assess the differences between readings of the same slides by different systems compared to repeated readings of the same system. There were no clinically significant differences between Duet systems of inter-system precision.

E. Other Supportive Information:

F. Conclusion:

The Bio View Duet System is substantially equivalent to SlideScan™ manufactured by Applied Imaging (K001420), ACIS, manufactured by Chroma Vision Medical Systems, Inc. (K984188), BandView, manufactured by Applied Spectral Imaging (K012103), and manual microscopy.

