10.0 CERTIFICATIONS

10.1 Summary for Public Disclosure

Applicant:	Kowa Company Ltd. 3-4-14 Nihon-bashi Chuo-ku, Tokyo, Japan
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Device Trade Name:	Kowa LD-2000 Leukocyte Counter
Common Name:	Test for Residual WBC in Leukoreduced Blood Components
Classification Name:	Test for Residual WBC in Leukoreduced Blood Components
Equivalent Device:	Nageotte hemocytometer
Device Description:	The LD-2000 is a system comprised of proprietary single-use cuvettes, reagents containing a cell membrane lysing agent and nucleic stain, and instrument which combines image analysis and operating software. The operational characteristics of the system allow higher through-put of samples/hour than Nageotte and flow cytometry methods of cell counting, and its use by laboratory workers trained in small volume pipetting and basic computer skills.
Intended Use:	The LD-2000 is intended to enumerate residual leukocytes in leukocyte reduced blood products for quality control.

Comparison:	The LD-2000 is substantially equivalent to the Nageotte hemocytometer in intended use, the utilization of nucleic stains for identifying leukocytes and in preclinical and clinical test performance (see below). The LD-2000 is comparable to FacSCAN Flow Cytometry with the Leukocount Kit in intended use, in automated features, the use of propidium iodide stain, and requirement for quality control reagents.
Non-Clinical Performance Data:	Precision studies on 10-20 replicates from 10 samples from Red Blood Cell products and 10 samples from Platelet Rich Plasma products demonstrated acceptable within-sample reproducibility. Coefficients of variation (CV) ranged from 8.1% to 37.7% and tended to be lower as leukocyte concentration in the sample increased, and in platelet rich plasma samples. Similar CV's have been found with Nageotte counting and other methods for detecting rare (low probability) events in clinical samples.
Clinical Data:	Results of clinical testing of over 400 quality control samples in three US licensed blood centers (approximately 300 Nageotte tests and 100 flow cytometry tests) demonstrated approximately 99% agreement between the LD-2000 and the validated QC methods. Testing of a contrived, encoded panel demonstrated the ability of all methods to detect excess leukocytes in unfiltered blood products and showed concentration-associated trends for contrived samples in the range of 1 to 7 x 10^6/product. The majority of LD-2000 panel results were at or above the target values and the majority of QC method results were at or below the target values.
Conclusion:	The LD-2000 Leukocyte counter is an acceptable alternative to Nageotte and flow cytometry leukocyte counting methods for the quality control of leukocyte reduced blood products.