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Exhibit 14
Summary of Safety & Effectiveness

The ***Spirit*** ***tm*** , is a computerized, enhanced electronic Hematology System designed for clinical applications to allow 16 whole blood parameters to be measured by a small table top computer driven instrument. BioChem Immunosystems Incorporated has a history of developing such systems and offers this device as a technological innovation over conventional Hematology Systems. This device is designed for use in small to medium clinics. As such, this device is a Class II device, having Classification Name: Electronic Hematology System, Product Code: 81GKZ as described in 21 CFR Part 864.5220. **BioChem Immunosystems Incorporated** has determined that this device is substantially equivalent to a ***predicate*** medical device which is currently in commerce and has been submitted to the FDA via K911626/B as an electronic Hematology instrument and is identified as the System ***9000 Plus, (Model 9018)*** also marketed by BioChem Immunosystems Incorporated.

A determination of substantial equivalence is based upon:

This device uses the same tried and proven chemistry but with fewer hardware parts. Instead of one computer, this new instrument would use three computers, each with a separate task as the process continued. The ***Spirit***™ uses more computers and less plumbing. Each process yields a higher throughput of analytical data resulting in a system easier to use, lower in cost and easier to maintain in the field.

The ***Spirit***™ *Hematology System* is a microprocessor based device which is designed to provide *identically the same clinical function* as the the System ***9000 Plus, (Model 9018)***. This compact device sits on any desktop. However, in addition, it provides a faithful analysis and display of key blood cells parameters by automatic processing and analyzing multiple samples and outputing test results via a structured computer program. Both the ***Spirit***™ and the System ***9000 Plus, (Model 9018)*** retain an electronically stored data and act on that data using mathematical computations {proprietary algorithm}and computer programming {stored in a Electronic media and PROM}to provide blood parameters.

Both the ***Spirit*** ***tm*** and the System ***9000 Plus, (Model 9018)*** are designed to measure multiple whole blood parameters during an unattended mode. Both provide the same acoustic qualities as the conventional mechanical Hematology System. Both devices retain a electronically stored sample and act on that sample using mathematical computations {proprietary algorithm}and computer programming stored in electronic memory to count whole blood parameters and issue measurements data relating to a specific patient/session for analysis. Neither device has claims or, is offered as, laboratory analysis equipment. Where either device is used, traditional medical practice requires additional analysis for any authentic diagnosis.

The ***Spirit*** ***tm*** provides a facility to analyze whole blood on a repeatable basis with conventional accuracy.
as also does the System ***9000 Plus, (Model 9018)***.

The ***Spirit*** ***tm*** has benefited from design, development, testing and production procedures that conform to Good Manufacturing Procedures. This device has performance characteristics substantially equivalent to its predicate device yet includes improvements to facilitate the various clinical applications for which it is intended.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy **BioChem Immunosystems Incorporated** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:
I hereby certify that this **Summary of Safety and Effectiveness** applies for the above indicated device.

12/27/95
Date Signed

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