

BK980003

510(k) Summary

1. **Name of Submitter:** Sanguin International Limited
1020 Sherman Avenue
Hamden CT 06514
 2. **Name of Manufacturer:** Sanguin International Limited
The Deer House
Dunstall Road
Barton-under-Needwood
Staffs DE13 8AX
UK
 3. **Establishment registration Number:** 12-23-644
 4. **Trade name:** Aurora / Fenestra
Common Name: Aurora / Fenestra
Trade Marks: Aurora and Fenestra are both registered trade marks of Sanguin International
 5. **Device Classification and product Code:** 81MMH
 6. **Performance Standards:** None
 7. **Intended Use:**

Sanguin Aurora is a computer software product for use on IBM compatible Personal Computers with a Graphical User Interface. The software can be used with microplate endpoint reading photometers (CFR 862.2300, panel 75JJQ) for the data reduction of Optical Densities provided from the reader. The data is interpreted into results from assay determinations of the following types: Qualitative ELISA, Quantitative ELISA, Haemagglutination, Blood Group Antigens, Blood Group Antibodies. In addition the software provides for sample management and reporting.
 8. **Indicated Use:**

The Software's indicated use is in the Blood Bank and Donor Center Testing Laboratory as well as Clinical Diagnostic Laboratories. It may be applied to a panel of tests that are employed to Screen Blood Donations for infectious disease as a prerequisite to transfusion. Typically these tests would include Hepatitis Markers, and HIV.

ABO Grouping and Rhesus Typing for Donor Typing, Confirmation and Patient Typing in addition to Antibody Screening for Donor and Patient Antibody Screening.
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9. Description:

Aurora has been specifically produced for Microsoft 32-bit operating system and offers a practical approach, to both the immediate requirement of producing results from microplate assays, to the more in depth considerations of data storage, validation and export of data.

Aurora is specifically designed for Laboratory Management using a variety of laboratory instrumentation. The graphical approach is designed to ensure the system is easy for all users to use. Export of validated results can be achieved either directly or indirectly to other computers or instruments and printers via the reporting function.

10. Substantial Equivalence:

Aurora is substantially equivalent to Sanguin Medusa 2000 in that:

Similarities:

- a.) Both systems permit transfer of data from one or more instruments.
- b.) Both systems track test results linked to specimen number
- c.) Both systems utilize password protection
- d.) Both systems allow user definition of assays
- e.) Both systems allow user to define calculation algorithms
- f.) Both systems allow user definable reports
- g.) Both systems are software only applications
- h.) Both systems have the same intended use

Differences:

- a.) Unlimited number of assays in Aurora
 - b.) Graphical User interface in Aurora
 - c.) Hyperlink Help facility
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