

Section 4. 510(k) Summary of Safety and Effectiveness

4.1 Submitter Information

Submitter: American National Red Cross
1616 N. Ft. Meyer Drive
Rosslyn, VA 22209
(phone): 703-807-5214 (fax): 703-351-5948

Contact: Gary Dolch, Senior VP, Quality and Regulatory
Affairs.

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4.2 Name of Device Classification

Name: National Genome Testing Laboratory (NGTL)
Automation System (NAS) Release 5.2.0

Common or Usual Name: Blood Banking Software

Classification Name: Software, Blood Bank, Stand Alone Products

4.3 Predicate Device

NAS is substantially equivalent and compares to the following software system:
Surround System, 2.0, BK000016.

4.4 Description of the Device

NAS is software designed to receive blood sample information, track blood samples, and record automated and/or manual test results. Once test data is collected in the NAS software, authorized users can search, display, create, and print test results. NAS establishes and maintains relationships between blood samples and test results and then transfers these results to other ARC Information Systems.

4.5 Intended Use

NAS is data management software which is not intended to perform any interpretations of test results, but rather it is intended to assemble and correlate automated and/or manual test results by unique identification number from blood samples. NAS blood-testing information can include information pertinent to

collections, sample/pool tracking, results management, administration, reporting, and test process turnaround statistics. NAS is a computerized system intended to be used by trained personnel as an aid in the collection, collation, and management of data generated by laboratory testing of blood samples.

4.6 Comparison to the Predicate

ARC has determined that NAS is substantially equivalent to the existing Information Data Management's Surround System 2.0 as identified in the table below. Substantial equivalence is claimed after determining that both the NAS System and the Surround System have the same intended use but different technological characteristics.

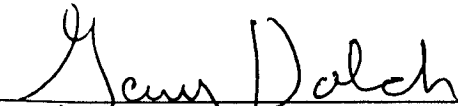
Applicant	Device Name	510(k) Number	Clearance Date
Information Data Management (IDM) 9701 West Higgins Road Rosemont, IL 60018	Surround System 2.0, Blood Banking Software	BK000016	4/7/2000

4.7 Performance Data

Non-clinical testing followed a master validation strategy in order to determine that NAS consistently performed as intended. Testing was divided into subsystem level testing (unit, integration, functional testing) and system level testing. A simulated blood bank test bed was established, test protocols developed, executed, and result data was collected and analyzed (See Section 9, Verification, Validation and Testing). The system was tested on a Windows '95 and NT platform connected via a Local Area Networks (LANs) to a Wide Area Network (WAN). Clinical data was not used to determine substantial equivalence.

4.8 Performance Data Conclusions

The results of the performance testing demonstrate that the device is as safe and effective as the predicate device.



Gary Dolch,
Senior VP, Quality and Regulatory Affairs

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Date