5.   510(k)   Summary

5.1   Submitter's Name

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03/20/1996

5.3   Device Name

SMS Blood Bank Transfusion System

5.3.1   Common Name

Blood Bank Transfusion System, (BBTS)

5.4   **Identification of Legally Marketed Predicate Devices**

The Blood Bank Management System
The preamendments device on which this submission is based is:
(Proof of preamendments status is included in exhibit 2)

Manufactured by:
Advanced Medical Systems, (AMS)
36 Maple Ave.
Rockville Center, NY

The legally marketed device on which this submission is based is:

FlexiLab Blood Bank Transfusion System
Manufactured by:
Sunquest Information Systems Inc.
4801 East Broadway
Tucson, AZ 85711

5.5   **Summary of Device Description**

The Blood Bank Transfusion System consists of seven separate but
interrelated application software modules:

1) Blood Processing
2) Patient Processing
3) Inventory Management
4) Recipient History
5) Reports
6) Purge Processing
7) File Maintenance

The major component of the SMS Blood Bank System is a SMS
developed application software that runs on general purpose hardware
platforms supplied by commercial manufacturers.

The Blood Bank Transfusion System is written in MUMPS.
Information is stored using MUMPS globals as a database. The SMS
blood bank database contains information about patient
antibodies/antigens, transfusion history, blood unit disposition and current
status as well as statistics, audit trail, and user logon information. This

information is maintained in the database for a customer defined length of time.

5.6 **Intended Use**

The Blood Bank Transfusion System provides a variety of functionality
for blood bank professionals. In essence the software
provides a mechanism for maintaining blood inventory records, the entry
of patient results such as Antibody Screens, Compatibility Testing and the
printing of Compatibility Slips. Additionally, the system provides an
electronic storage area for patient recipient histories as well as a hard copy
down time record retrieval system. The functionality is designed to allow
for increased oversight via an audit trail, as well as enhance patient safety
through the use of warning messages and integrity checks. The testing
guideline that was used to test the system is included in this application,
test data will be available upon request.

This system is not designed for, nor is it intended in anyway to
be used for recording of donor information or for the association of
infectious disease testing with any donor or donor unit.

5.7 Information and data Supportive of Substantial Equivalence Claim to AMS Blood Bank Management System and the Sunquest FlexiLab Transfusion System

Comparison Table

AREAS OF COMPARISON	SIMILARITIES	DIFFERENCES
1. Product labeling	AMS, FlexiLab Transfusion System and the SMS are designed to be used in a Lab Transfusion Service	
2. Intended Use	The AMS, FlexiLab and SMS Blood Bank Transfusion systems are to be used by laboratory professionals to record the results of common blood bank tests, i.e., antibody screens, antibody identifications, crossmatches, and blood group and type. Additionally, AMS, FlexiLab Blood Bank Transfusion, and the SMS Blood Bank systems allow for the electronic storage of this information as well as electronic storage of information associated with blood components, their use in crossmatches, status and disposition.	
3. Hardware Platform	SMS - DEC Alpha/VAX FlexiLab - DEC Alpha/VAX	AMS - DEC PDP11
4. Software Language	SMS, AMS and FlexiLab are all written in MUMPS	

5. Software Functionality	SMS, AMS and FlexiLab are all designed to record blood component login identification, group/Rh, supplier identification, expiration date. Record the results of patient testing. Display patient historical files Create statistical reports based on blood usage, crossmatch to transfusion ratios.	
6. Input	The SMS, AMS and the SMS Blood Bank Transfusion systems utilize a keyboard for input. SMS and FlexiLab - Bar-code Scanner and keyboard	AMS- no Bar-code Scanner
7. Output	The AMS, FlexiLab and SMS Blood Bank Transfusion systems use CRT's and Moderate - High Speed Printers for output	
8. Safety Characteristics	The AMS, FlexiLab and SMS Blood Bank Transfusion systems prompt users when unusual conditions exist. Each system captures identification of individuals performing tasks and display patient information while patient testing is underway. SMS and FlexiLab provide bar coding capabilities that reduces/eliminates clerical errors SMS and FlexiLab provide audit trail for supervisory review.	AMS did not provide bar coding capabilities nor does it provide for auditing of unusual events by supervisory review.