Section 7
Summary of Safety and Effectiveness

510(K) SUMMARY

MANUFACTURER SUBMITTING 510(K) SUMMARY:

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DEVICE NAME:

> Proprietary Name: HCLL™, Version 3.0
> Common Name: Software, Blood Bank, Stand Alone
> Classification: Product is not classified.

PREDICATE DEVICE:

> HCLL™, version 2.6

DEVICE DESCRIPTION:

> HCLL™ is a stand-alone blood bank software device that aids in the management of single, multi-site, or centralized transfusion services.

INTENDED USE:

> HCLL addresses all transfusion services activities involved in registration and tracking of blood recipients and manufacture and distribution of blood and blood products including:

> HCLL™ Transfusion, version 3.0 is intended to address all phases of transfusion services activities, and assists transfusion service

Section 7
Summary of Safety and Effectiveness

personnel:

- Maintain a reliable patient database

- Manually and electronically register, admit and transfer patients

- Manually and electronically receive patient orders

- Manipulate and label products

- Print ABC Codabar and ISBT 128 blood labels

- Perform electronic crossmatch

- Issue blood products under normal and emergency conditions

- Receive inventory

- Ship specimens, reagents, derivatives and blood products

- Receive and test patient and unit specimens

- Interface to blood bank testing instruments (bi-directional)

- Interface to blood storage devices (bi-directional)

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICES:

The intended uses and technological characteristics of HCLL™ are comparable to the predicates. The systems are fully scalable to the enterprise level and the relational database management systems, operating systems and hardware are substantially equivalent.

SAFETY AND EFFECTIVENESS DATA:

The HCLL System was developed using a documented procedure for software development based on the Quality Systems Requirements. Safety and Effectiveness of the finished device was validated and verified through internal and external testing processes.
The assessment of non-clinical testing demonstrated that the HCLL design input requirements were met. The design validation process demonstrated that HCLL meets the requirements for its intended use. Clinical/user site testing was conducted to validate that he HCLL software performs as expected. The results of the testing demonstrated that HCLL software meets the required specifications and functioned as expected.

CONCLUSION:

Internal and external evaluation, validation and verification, demonstrate that HCLL™, version 3.0, is substantially equivalent to

Section 7
Summary of Safety and Effectiveness

the predicate device(s) when utilized with its intended use.