## MANUFACTURER SUBMITTING 510(K) NOTIFICATION:

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## DEVICE NAME:

Proprietary Name:     HCLL®, Release 2.6
Common Name:          Software, Blood Bank, Stand Alone
Classification Name:  Unclassified

## PREDICATE DEVICES:

Cerner PathNet Blood Bank Transfusion, version 306
SoftBank® II, version 21.1
LifeTrak®/Lab, version 2.03

## DEVICE DESCRIPTION:

The HCLL System 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 phases of transfusion services activities, and helps transfusion service 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

- Test patient and units specimens

- Interface to blood bank testing instrument

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE:

The technological characteristics are similar in that the systems are fully scalable to enterprise level and that the RDBMS, operating system and hardware are substantially equivalent to the predicate devices.

## SAFETY AND EFFECTIVENESS DATA:

The HCLL System was developed using an established procedure for software development.

The assessment of the nonclinical (alpha) testing is that the HCLL System design input requirements had been met. The design validation process demonstrated that the HCLL System meets the requirements for the intended use.

Clinical/user site (beta) testing was conducted to validate the HCLL software. Testing was conducted at three different clinical facilities. The results of the beta testing demonstrated that the HCLL software met the required specifications and functioned as expected.

## CONCLUSION:

The conclusions drawn for the nonclinical and clinical tests demonstrate HCLL, Release 2.6, is substantially equivalent to the predicate device(s) when utilized within its intended use.