

2. 510(k) SUMMARY

Prepared: March 31, 2008

2.1 MANUFACTURER SUBMITTING 510(k) SUMMARY

LifeSouth Community Blood Centers, Inc.
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2.2 CONTACT PERSON

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2.3 DEVICE NAME

Trade Name: Integrated Blood Bank Information System, version 1.0
(IBBIS)
Common Name: Blood Banking Software
Classification: Software, Blood-Bank, Stand Alone Products

2.4 PREDICATE DEVICES

Wyndgate Technologies, SafeTrace Version 1.0 (BK950059)

2.5 DEVICE DESCRIPTION

The IBBIS system is a stand-alone blood bank software device which aids in the manufacture and distribution of blood and blood components by allowing the entry and tracking of information related to blood donor registration.

2.6 INTENDED USE

IBBIS is a computerized system of wizard-based programs intended for use by trained LifeSouth personnel. The system is to be used solely by the staff of LifeSouth Community Blood Centers, Inc.

2.7 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Item	Wyndgate SafeTrace v1.0	IBBIS v1.0
Intended Uses	A relational database for use in blood establishments to track, report, and offer control logic, which help to maintain blood and blood product quality and safety	The same intended use, but limited to functionality related to donor and patient registration
	Provide donor and donation history information	Same as predicate device
	Manage donor deferrals	Same as predicate device
	Assign a unit number to each donation	Same as predicate device, and ensures uniqueness by using the ISBT 128 standard
	Manual (keyboard) interface or bar code entry	Same as predicate device
	Access security through password and username	Same as predicate device
Indications for Use	The registration of donors and functionality related to registrations	Same as predicate device, but limited for use by LifeSouth Community Blood Centers, Inc. only
Target Population	Trained customer personnel	Trained LifeSouth Community Blood Center, Inc. users
Where Used	Donor centers and blood mobiles	Same as predicate device
Design	Graphical user interface; relational database; reporting capability	Same as predicate device
Performance	Equal to the needs required of its users	Same as predicate device

2.8 SAFETY AND EFFECTIVENESS DATA

LifeSouth followed an established software development procedure to develop IBBIS version 1.0. This system will be as safe, as effective, and will perform as well as the predicate device when utilized within its intended use, as demonstrated by the verification and validation testing performed. The assessment of the results of verification (unit/integration and system testing) and validation can be found in sections 11 and 12 of this submission.