



510(k) Summary

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Submitter

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Contact

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Device Information

TRADE Name: SafeTrace Tx® Software
Common Name: Blood Establishment Computer Software
Classification Name: Blood Establishment Computer Software and Accessories
Regulation Number: 21 CFR 864.9165
Review Panel: Hematology
Product Code: MMH
Device Class: 2

Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
BK180209	SafeTrace Tx 4.0.0	MMH

Device Description Summary

The SafeTrace Tx® software is a web-based electronic information system designed to support single, multi-site or centralized transfusion service operations in determining the suitability of blood and blood components for release. The software application maintains a complete test and transfusion history for a patient and enables end-to-end management and traceability of blood and blood components from receipt through final disposition.

Intended Use

The SafeTrace Tx® software is a web-based electronic information system intended to manage transfusion service operations and assist in the determination of the suitability of released products. The software application maintains a complete test and transfusion history for a patient and manages and tracks blood and blood components from receipt to final disposition. The SafeTrace Tx software provides the following functionality:

- Performs electronic crossmatching and safety and compatibility checks between patient and product.
- Provides information to assist in the determination of the suitability and compatibility of blood and blood components with potential recipients.
- Helps prevent the release of unsuitable or incorrect blood and blood components for potential recipients and for further manufacturing.



Indications for Use

The SafeTrace Tx ® software is a web-based electronic information system that;

- Performs electronic crossmatching and safety and compatibility checks between patient and product.
- Provides information to assist in the determination of the suitability and compatibility of blood and blood components with potential recipients.
- Helps prevent the release of unsuitable or incorrect blood and blood components for potential recipients and for further manufacturing.

Indications for Use Comparison

The Indications for Use for the SafeTrace Tx Software have been clarified to describe only the medical functionality and to remove non-medical functionality, which were not critical to the safety and effectiveness of the software device when used as labeled. Indications related to medical functionality are the same for the SafeTrace Tx 5.0.0 and the predicate, SafeTrace Tx 4.0.0 (BK180209).

Technological Comparison

There is no change to the underlying technology, or principle of operation from the predicate SafeTrace Tx 4.0.0 (BK180209). The device functions with the same intended use to support single, multi-site or centralized transfusion service operations in determining the suitability of blood and blood components for release. Through the discussion on substantial equivalence, the risk management documentation, and the testing provided, it is concluded that the changes associated with SafeTrace Tx 5.0.0 do not change the risk-benefit profile of the SafeTrace Tx Software.

Non-Clinical and/or Clinical Tests

The non-clinical testing performed to support this premarket submission was performed in accordance with the FDA Guidance, *General Principles of Software Validation (2002)*. The software testing consisted of thorough verification and validation testing to ensure the subject device is as safe, as effective, and performed as well as or better than the predicate device.

No clinical testing was performed in support of this premarket submission for the SafeTrace Tx Software.

Summary & Conclusions

The non-clinical testing and comparison to the predicate device show the subject SafeTrace Tx 5.0.0 software to be substantially equivalent to the predicate device and that there is no impact to the safety and effectiveness of the device.

Results from the non-clinical testing demonstrate that the SafeTrace Tx 5.0.0 software is as safe and effective, and it performs as well as its proposed predicate device.

In conclusion, the SafeTrace Tx 5.0.0 software is substantially equivalent to the predicate device in terms of functionality, performance, technological characteristics, and Indications for Use, including for safety and effectiveness.