SECTION E: 510 K Summary

1.1: **Manufacturer:**

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1.3: **Device Name:**

Proprietary Name: CareChek Patient Identification System
Common Name: CareChek ^{TX}
Classification: Blood Bank Software, Stand Alone Products

1.4: **Predicate Device:** BK980023 Wyndgate Technologies

1.5: **Device Description/Intended Use:**

The CARECHEK Patient Identification System is a computerized handheld system intended for use by hospital professionals to assist in the proper identification of patients, specimens, blood products for transfusion and medications to be administered.

The CareChek System is based on a modular design:

CareChek ^{TX} – Blood Product Administration

- The CareChek system offers solutions to enhance patient safety through the use of bar code technology to provide proper patient identification at the bedside.
- The system receives and manages orders placed from a remote system
- The system incorporates system-controlled logic that requires a positive scan of patient, blood products and compares that information against that received from the remote host.

- The system documents patient identification.
- The system documents blood product identification, patient vitals taken during administration and AABB defined Transfusion Requirements.

1.6: Comparison of Characteristics of CareChek Patient Identification System to Predicate Device:

AREAS OF COMPARISON	CARECHEK	SAFETRACE TX
Patient Identification - Verification of Patient Identification through use of unique number.	✔	✔
Product Identification – Provides product verification through bar code scanning that correct product was assigned to correct patient prior to administration.	✔	✔
Order Management- manages orders for blood product administration.	✔	✔
User Friendly GUI	✔	✔
Centralized Application	✔	✔
Table Maintenance – allows user with security authorization to add, update, and edit data. Provides functionality to build user defined tables.	✔	✔
Clinical Error Messages	✔	✔
Exception/Override Captures	✔	✔
Security- Maintains User ID and password combinations. Manages access to system. Maintains login histories.	✔	✔

AREAS OF COMPARISON	CARECHEK	SAFETRACE TX
Report Generation – Provides a standard set of reports	✔	✔

The software functionality of the CareChek [TX] application is substantially equivalent to the Wyndgate Safetrace TX application.

Technological Characteristics between CareChek and predicate device:

AREAS OF COMPARISON	CARECHEK	SAFETRACE TX
	✔	✔
Barcode Scan Capabilities		
Mobile Bedside Device	✔	
Application Server.	Microsoft Windows XP	Microsoft Windows NT Server
Operating system	Handheld Server Windows XP (SR1) Pentium 4 desktop (500 MB minimum memory), 40 GB hard disk minimum, with the following additional software installed: .NET Framework v1.1 Microsoft Internet Information Server (IIS) Microsoft SQL Server Desktop	Microsoft Windows 95 or higher or Windows NT or higher

AREAS OF COMPARISON	CARECHEK	SAFETRACE TX
	Engine (MSDE)	
	Handheld Device	
	Pocket PC 2003	
Database	Microsoft SQL Server Desktop Engine (MSDE, installed and configured by the application install)	Oracle Relational Database Management version 7.3 or higher

The operating system, database and hardware characteristics of the CareChek TX application are different but substantially equivalent to the Wyndgate Safetrace application.

1.7: Safety and Effectiveness Data:

The CareChek Patient Identification System was developed using an established procedure for software development.

This system will be safe, effective and perform as well as the predicate device when utilized within its intended use, as demonstrated by the clinical and non-clinical

The assessment of the non-clinical testing is that the CareChek Patient Identification System design input requirements have been met. The design validation process demonstrated that the CareChek Patient Identification System meets the requirements for the intended use.

Clinical/user site testing was conducted to validate the CareChek Patient Identification System software. The results of this testing demonstrated that the CareChek Patient Identification System software met the required specifications and functioned as expected.