## R. 510(k) Summary of Safety and Effectiveness

| I. General Information<br>This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 § 807.92 | |
|---|---|
| Establishment: | |
| • Address: | BD Diagnostics, Preanalytical Systems<br>1 Becton Drive<br>Franklin Lakes, NJ 07417-1885 |
| • Registration Number: | 2243072 |
| • Contact Person: | M. Wendy Ballesteros<br>Regulatory Affairs Specialist<br>Telephone no.: 201-847-6280<br>Fax No. 201-847-4858 |
| • Date of Summary: | July 28, 2006 |
| Device | |
| • Trade Name: | BD.id™ Patient Identification System for Transfusion Management |
| • Classification Name: | Software, Blood Bank, Stand Alone Product |
| • Classification: | Class II |
| • Performance Standards: | None Established under 514 of the Food, Drug and Cosmetic Act |

## II. Safety and Effectiveness Information Supporting Substantial Equivalence

- Device Description

The BD.id Patient Identification System for Transfusion Management is a software application that is designed to be used in a client server environment, along with the following Hardware components: BD.id System Server, an interface using the Health Level Seven (HL7) and a handheld portable data terminal (PDT) and a PDT docking station. The PDT has an integrated barcode scanner/reader, an interactive touch screen display, user interface buttons (scan, scroll up/down; power and display contrast), and audible alarms.

- Intended Use

The BD.id™ Patient Identification System for Transfusion Management is to provide a positive identification match between the blood products to be transfused, the intended patient for which the blood product was issued, and verifying this information against the information issued by the Blood Bank Information system (BBIS). This positive identification match is performed at the bedside prior to transfusion, thus aiding in the prevention of transfusion errors.

The BD.id System for Transfusion Management software also allows additional functions such as identification of the healthcare professional who verifies the information prior to transfusion; collection of data such as transfusion start time, transfusion complete time, amount transfused, reason codes for a terminated transfusion. These data, as well as various reports (e.g. exception reports), can be accessed from the server via web pages on a desktop PC.

- Synopsis of Performance Study Results

Validation testing was performed to confirm the robustness of the design and reliability of the safety feature function. Simulated use testing was performed to evaluate the function within the blood transfusion environment.

III. Predicate Device Summary Table

- Substantial Equivalence

Based on comparison of the device features, intended use and operating principles, the BD.id™ Patient Identification System for Transfusion Management is shown to be substantially equivalent to the commercially available predicate devices indicated in the table below. The predicate devices, K number, and clearance date are also identified in the table below.

| Manufacturer | Predicate Device | K-Number |
|---|---|---|
| Care Fusion | wBloodCare™ | BK040002 |
| Sunquest Information Systems, Inc. | FlexiLab Blood Bank and Blood Donor System 5.2 | BK990034 |

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July 28, 2006
Date