

(4) 510(k) Summary

SECTION E: 510 K Summary

1 . 1 :	Manufacturer:	BIQ Health Solutions, Lda Rua Ferreira de Castro – 20C 2730-081 Barcarena - PORTUGAL (office) +351 213 432 600
1 .2:	Contact Person:	Gonçalo Mergulhão International Sales Director Rua Ferreira de Castro – 20C 2730-081 Barcarena - PORTUGAL (office) +351 213 432 600
1 .3:	Device Name:	BTrac
	Proprietary Name:	BTrac
	Common Name:	BTrac
	Classification:	Blood Bank computer software and accessories 21 CFR 864.9165
1 .4:	Predicate Device:	BK040053, CareChek Patient Identification System Version 1.0

1 .5: Device Description/Intended Use:

BTrac is a computerized handheld system intended for use by hospital professionals to assist in the proper identification of patients, specimens and blood products for transfusion.

BTrac main features

- BTrac 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 and patient vitals taken during administration

1 .6: Comparison of Functional Characteristics of BTrac to Predicate Device:

	BTrac	CareChek Patient Identification System Version 1.0
Patient Identification – Verification of Patient Identification through barcode scanning	✓	✓
Order Management – Management and reception of electronic orders from remote systems	✓	✓
Specimen Collection Identification – Verification and match of specimen collection through barcode scanning	✓	✓
Product identification – Provides product verification through barcode scanning that correct product is being given to the correct patient	✓	✓
User friendly Graphical User Interface	✓	✓
Parameters management – Allows user with security authorization to add, edit and update data.	✓	✓
Clinical Error messages	✓	✓
Reports – Provides transfusion report to third party system.	✓	✓

The software functionality of the BTrac application is substantially equivalent to the predicate device, CareChek TX application.

1.7 Technological Characteristics between BTrac and predicate device:

	BTrac	CareChek Patient Identification System Version 1.0
Patient Identification – Verification of Patient Identification	Hospital professionals	Hospital professionals

through barcode scanning		
User Population	Hospital professionals	Hospital professionals
Communication with External Systems	Receives information from an external blood bank system via an HL-7 interface Communicates information to an external system via HL7 interface	Receives information from a remote system via an HL-7 interface and communicates documentation to a remote host
Barcode Scanning Capabilities	Yes, must be used with a barcode scanner	Yes, must be used with a barcode scanner
Blood Product Matching	Incorporates system-controlled logic that requires a positive scan of a patient and a blood product and compares that information against information received from the remote host	Incorporates system-controlled logic that requires a positive scan of a patient and a blood product and compares that information against information received from the remote host
Specimen Management	Specimen tracking and matching	Specimen tracking and matching
Information Storage	Does not store blood administration and related information, but transmits this information back to the remote host(s) for storage	Stores blood administration and related information, and also transmits the information back to the remote host(s) for storage
Hardware	Handheld device Server Workstation capable of running a browser	Handheld device, server, and PC workstation
Mobile Bedside Device	Yes	Yes
Operating system	HD- Android OS Server - Microsoft Windows Server Workstation – Agnostic OS	<ul style="list-style-type: none"> • Handheld Server • Windows XP (SR1) Pentium 4 desk-top (500 MB minimum memory), 40 GB hard disk minimum, with the following additional software installed:

		<ul style="list-style-type: none"> • .NET Framework V1.1 • Microsoft Internet Information Server (IIS) Microsoft SQL Server Desktop Engine
Application Server	Microsoft Windows Server	Microsoft Windows XP
Handheld requirements		
Operating System(s)	Android v8.1	Microsoft PocketPC 2003
Hardware	Recommended: Honeywell EDA 51 Zebra T51	Symbol PDA
Application Language	Java, C# and VB.Net	C++
Database	Microsoft SQL Server and SQLite	Microsoft SQL Server Desktop Engine

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

1.8: Safety and Effectiveness Data:

The BTrac system was developed using an established procedure, IEC 62304 for software development.

This system is as safe, effective and perform as well as the predicate device when utilized within its intended use, as demonstrated by the Software verification and validation activities performed.

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

1.9. Conclusion

The devices described in this submission: BTrac is substantially equivalent to the predicate devices based on intended usage, technology comparison and performance. The nonclinical tests (discussed above) demonstrate that the device is as safe and effective.