

510(k) Summary for BK220673

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

1. Submitter's Information

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2. Subject Device Information

Type of 510(k): Traditional

Classification Name: Transfer Sets

Trade Name: Sterile Tube Welder

Model Name: STW6810-RFID

Review Panel: Hematology

Product Code: KSB

Regulation Number: 21 CFR 864.9875

Regulatory Class: II

3. Predicate Device Information

Sponsor: Terumo BCT, Inc

Trade Name: TSCD®-II Sterile Tubing Welder with or without Trucise Total System™

Classification Name: Transfer Sets

510(K) Number: BK170098

Review Panel: Hematology

Product Code: KSB

Regulation Number: 21 CFR 864.9875

Regulation Class: II

4. Device Description

The Sterile Tube Welder (STW6810-RFID) is to install the tube holder, blade and hose into the equipment, start the touch screen, and the aseptic connection procedure will run automatically. The blade is first heated to remove the heat source and then cooled to the welding temperature. The infrared sensor monitors and controls the temperature of the blade during the entire operation. When the welding temperature is reached, the blade cuts the hose and a new liquid path connection is formed, so that connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components.

These welds may consist of dry-to-dry, wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications.

The device consists of a main unit, a blood bag tray, a [metal wire cassette](#), and an AC power cord. After connecting to the power supply, the preheating is completed and the [tube](#) that need to be connected are placed, click to start connection, and then wait for the connection to be completed.

The Sterile Tube Welder is not to be used with tubing connected to a person. This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

5. Intended Use / Indications for Use

The Sterile Tube Welder (STW6810-RFID) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry, wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications.

The Sterile Tube Welder is not to be used with tubing connected to a person. This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.

6. Test Summary

6.1 Summary of Non-Clinical Tests

Sterile Tube Welder has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 61010-1 standards

- Electromagnetic compatibility test according to IEC 61326-1 standard
- Performance test according to ISO 3826-1 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

6.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

6. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Sterile Tube Welder is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Wuhan BMS Medicaltech Co., Ltd	Terumo BCT, Inc	--
Trade Name	Sterile Tube Welder	TSCD®-II Sterile Tubing Welder with or without Trucise Total System™	--
Models	STW6810-RFID	--	--
510(k) Number	BK220673	BK170098	--
Classification, Indications for Use and Intended Use			
Classification Name	Transfer Sets	Transfer Sets	Same
Classification Product Code	KSB	KSB	Same
Intended Use / Indications for Use	The Sterile Tube Welder (STW6810-RFID) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry,	The Terumo Sterile Connecting Device (TSCD®-II) is used to connect two closed internally sterile components such as a blood collection container, apheresis set, transfer set or needle set by making a sterile weld in the tubing connected to these components. These welds may consist of dry-to-dry,	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device	Verdict
	<p>wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications. The Sterile Tube Welder is not to be used with tubing connected to a person. This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.</p>	<p>wet-to-dry or wet-to-wet connections. The resulting sterile component may be used in blood collection, blood component processing or transfusion applications. Uses include, but are not limited to:</p> <ul style="list-style-type: none"> • Attaching additional blood component containers to a blood collection set to enable component separation or division of the original component into smaller aliquots • Attaching containers of processing or additive solutions to a blood component to perform a process such as cell washing or freezing or to extend the storage time of the component • Attaching blood component containers to a pooling set to enable pooling of components from multiple donations • Attaching a leukocyte reduction filter to a red blood cell or platelet component container to enable removal of leukocytes from the component • Attaching a sampling pouch to a blood component container to enable the removal of samples of the component for testing 	

Elements of Comparison	Subject Device	Predicate Device	Verdict
		<ul style="list-style-type: none"> Replacing the original needle on a collection set with a new needle of the same or smaller gauge to enable the use of the set or to facilitate a therapeutic procedure such as plasma exchange <p>The TSCD-II device is not to be used with tubing connected to a person. This device is for use by trained individuals in such settings as blood bank laboratories and hospitals.</p> <p>The Trucise is an optional accessory information system device intended for use with the Terumo Sterile Tubing welder, TSCD-II, to electronically collect information and provide traceability of each sterile connection made by the welder.</p> <p>The system design and requirements add process control capability to the sterile connection process.</p>	
Environment of Use	Blood bank laboratories and hospitals	Blood bank laboratories and hospitals	Same
Technological Characteristics			
Dimensions	380(W) x 300(H) x 690(D) mm	224(W) x 177(H) x 342(D) mm	Different Note 2
Weight	13.8±0.5kg	6.5 kg	Different Note 2
Power supply	AC110V/60Hz	AC100V – AC240V 50/60 Hz	Similar Note 2

Elements of Comparison	Subject Device	Predicate Device	Verdict
Tubing material	Polyvinyl chloride (PVC) tubing	Polyvinyl chloride (PVC) tubing	Same
Outer Diameter (OD) of tubing	3.9mm-5.0mm	3.86 – 5.60 mm	Similar Note 3
Wall Thickness of tubing	0.5mm-0.7mm	0.508 – 1.10 mm	Similar Note 3
Outer Diameter (OD) of Blood Bag Type Tubing	3.9mm-5.0mm	3.86 – 4.60 mm	Similar Note 3
Wall Thickness of Blood Bag Type Tubing	0.5mm-0.7mm	0.508 – 0.800 mm	Similar Note 3
Outer Diameter (OD) of Apheresis Type Tubing	3.9mm-4.5mm	4.9 – 5.60 mm	Similar Note 3
Wall Thickness of Apheresis Type Tubing	0.5mm-0.7mm	0.75 – 1.10 mm	Similar Note 3
Weld strength	More than 40 N	More than 40 N	Same
Weld working temperature	280°C-320°C	290°C – 310°C	Similar Note 3
Weld cycle	Approximately 1 weld every 22 seconds	Approximately 1 weld every 14 seconds	Similar Note 3
Safety and Performance Testing			
Electrical Safety	IEC 61010-1	IEC 61010-1	Same
Electromagnetic Compatibility	IEC 61326-1	EN 61326-1	Same

Comparison in Detail(s):

Note 1:

Although the “Intended Use / Indications for Use” of the subject device and the predicate device are slightly different, the difference is that the subject equipment has no traceability system, and the main pipe welding functions and types are the same, which does not affect the safety and effectiveness of the device.

Note 2:

The “Dimensions”, “Weight” and “Power supply” of the subject device are different from the predicate device, all of them meet the requirements of safety and performance standard IEC 61010-1. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 3:

The “Outer Diameter (OD) of tubing”, “Wall Thickness of tubing”, “Outer Diameter (OD) of Blood Bag Type Tubing”, “Wall Thickness of Blood Bag Type Tubing”, “Outer Diameter (OD) of Apheresis Type Tubing”, “Wall Thickness of Apheresis Type Tubing”, “Weld working temperature” and “Weld cycle” of the subject device are different from the predicate device, all of them meet the performance requirements and passed the test. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

7. Final Conclusion:

The subject device Sterile Tube Welder has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device BK170098.