

## 5. 510(k) SUMMARY

(As required by 21 CFR 807.92)



<b>DATE</b>	July 14, 2021
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<b>TRADE NAME</b>	Genesis RapidWeld II STW, model GRW-430-02
<b>COMMON NAME</b>	Sterile Tube Welder
<b>DEVICE CLASSIFICATION</b>	Class II Transfer set (Blood/Plasma), per 21 CFR 864.9875 Product Code: KSB
<b>PREDICATE DEVICE</b>	BK140187 Genesis RapidWeld STW Sterile Tube Welder

### SUBSTANTIAL EQUIVALENCE

The Genesis RapidWeld II STW Sterile Tube Welder is substantially equivalent to their own predicate, Genesis RapidWeld STW Sterile Tube Welder BK140187. The Genesis RapidWeld II STW Sterile Tube Welder of this submission has the same product design and principles of operation and similar technological characteristics, that do not raise different questions of safety and effectiveness. In addition, the subject device Indication for Use is identical to the predicate device.

### TECNOLOGICAL CHARACTERISTICS

The Genesis RapidWeld II STW has similar technological characteristics when compared to their predicate device. Bench testing has demonstrated that the Genesis RapidWeld II STW is functionally equivalent to the BK140187 Genesis RapidWeld STW predicate device. Any minor differences do not affect safety or effectiveness of the Genesis RapidWeld II STW.

Feature	GenesisBPS RapidWeld II STW (model GRW-430-02) Subject Device	Genesis RapidWeld STW (model GRW-430) BK140187 Predicate Device
Manufacturer	GenesisBPS, LLC	GenesisBPS, LLC
Product Trade Name	Genesis RapidWeld II STW, Model GRW-430-02	Genesis RapidWeld STW, Model GRW-430
Device Common Name as Cleared by FDA	Sterile tube welder	Sterile tube welder
Classification #	Class II, 21CFR 864.9875	Class II, 21CFR 864.9875
Classification Name	Transfer set (Blood/Plasma)	Transfer set (Blood/Plasma)
Product Code	KSB	KSB
Device Description	The Genesis RapidWeld II STW, model GRW-430-02, is a medical device used in laboratories, designed for the purpose of making sterile connections in PVC tubing in blood processing applications. The device enables fluid transfer while maintaining a closed system without the need for a consumable (disposable wafer).	The Genesis RapidWeld STW, model GRW-430, is a medical device used in laboratories, designed for the purpose of making sterile connections in PVC tubing in blood processing applications. The device enables fluid transfer while maintaining a closed system without the need for a consumable (disposable wafer).
Principles of Operation	Provides a sterile weld between PVC tubing for wet to wet, wet to dry, and dry to dry connections with no wafer and no cartridge.  Process: 1. Tubes are clamped. 2. Tube ends are fluid-stripped and cut with blade. 3. Tube ends are heated with infrared (IR) source. 4. Tube ends are sterile welded.	Provides a sterile weld between PVC tubing for wet to wet, wet to dry, and dry to dry connections with no wafer and no cartridge.  Process: 1. Tubes are clamped. 2. Tube ends are fluid-stripped and cut with blade. 3. Tube ends are heated with infrared (IR) source. 4. Tube ends are sterile welded.
Fully Closed System	Yes	Yes
Tube Size	OD: 3.98mm – 4.88mm ID: 2.8mm – 3.23mm WT: 0.55mm – 0.85mm	OD: 3.95mm – 4.55mm ID: 2.8mm – 3.1mm WT: 0.55mm – 0.85mm
Tube Material for Welding	PVC	PVC

### DESCRIPTION OF THE DEVICE

The Genesis RapidWeld II STW, model GRW-430-02, is a medical device used in laboratories, designed for the purpose of making sterile connections in PVC tubing in blood processing applications. The device enables fluid transfer while maintaining a closed system without the need for a consumable (disposable wafer).

### INTENDED USE/INDICATIONS FOR USE

The Genesis RapidWeld II STW, model GRW-430-02, is used to make a sterile connection/weld between two segments of PVC tubing used in blood/blood component processing applications.

**PERFORMANCE DATA**

Performance testing and electrical safety testing demonstrate that the Genesis RapidWeld II STW performs its intended use and is substantially equivalent to the predicate device.

Description	Summary and Conclusion
Container Characteristics and Performance Testing	ISO 3826-1:2019 Acceptance criteria met
Electrical Safety	IEC 61010-1:2012 (revised 2018) and IEC 61010-2-010:2019 Acceptance criteria met  EN 61236-1:2013 Acceptance criteria met

**CONCLUSION**

Based on the design validation, verification, and performance testing, it can be concluded that the Genesis RapidWeld II STW, model GRW-430-02, is substantially equivalent to the predicate BK140187 Genesis RapidWeld STW, model GRW-430, with respect to intended use, principles of operation, design, and technological characteristics.