

510(k) Summary

510(k) Number K09

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Date Prepared: February 9, 2009

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1. Identification of the Device:

Proprietary-Trade Name: Biomixer BM330 with XBee (wireless) Option

Classification Name: Common/Usual Name: Blood Collection Scale and Mixer

Device Class/Product Code: Class II, Code MYJ.

- 2. Equivalent legally marketed device:** BK990013 Biomixer 330 and Biomixer 323, Ljungberg & Kögel AB
- 3. Indications for Use (intended use)** This device is for use only by a trained medical professional for blood collection and data registration.
- 4. Description of the Device:** This device is essentially identical to our original Biomixer 330 but it adds wireless communication with the host data collection computer. BM330 with an optional XBee module can be connected in a wireless network for online blood data collection. The XBee network works like a virtual wire connection, and no network setup or configuration is needed. The advantage is a quick setup, more flexibility when refurbishing and no need for expensive cable pulling. As many as 50 units can be connected at the same time, to the same data collecting PC. The range is approximately 40 meters. The XBee option uses radio signals to transfer data to the blood data collection PC, like a virtual wire. A radio network is created and many BM330 can use the same data collecting PC.
- 5. Safety and Effectiveness, comparison to predicate device.** The results of bench and test laboratory indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Characteristic	BK990013 Biomixer 330 and Biomixer 323	Biomixer BM330 with XBee (wireless) Option
Intended Use:	This device is for use only by a trained medical professional for blood collection and data registration.	SAME, unchanged.
Physical characteristics:		
Size/weight	290mm L x 253mm W x 150mm H; 4.8KG	SAME, unchanged.
Energy Source:	115/230 VAC or Internal Rechargeable battery	SAME, unchanged.
User Interface	LCD	SAME, unchanged.
Data Registration	Bar Code Reader, (optional)	SAME, unchanged.
Computer Interface	Serial RS-485/RS232	Wireless, IEEE 802.15.4 networking protocol for fast point-to-multipoint or peer-to-peer networking.
Standards and Safety characteristics:		
EMC	IEC 60601-1-2	SAME, unchanged.
Electrical safety:	IEC-60601, Class I, Type B	SAME, unchanged.

7. Conclusion

After analyzing bench and external laboratory testing to applicable standards, it is the conclusion of Ljungberg & Kögel AB that the Biomixer BM330 with XBee (wireless) Option is as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.