

EXHIBIT 2
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510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
Proprietary-Trade Name: Biomixer 330, Biomixer 323
Classification Name: DEVICE, BLOOD MIXING AND BLOOD WEIGHING,
Product Code KSQ
Common/Usual Name Scale/mixer for blood collection
2. Equivalent legally marketed devices This product is similar in design and function to the Hemo-Matic® Blood Collection Monitor
3. Indications for Use (intended use). This device is for used by a trained professional for blood collection and data registration.
4. Description of the Device: Biomixer BM 330 is a blood collecting, weighing and monitoring instrument for use in blood banks. It has a clamp function, which stops the blood flow when set volume has been reached. BM 330 has a barcode reader option for scanning identity of blood bags, donor, operator etc. It also can be connected to a local area network for communication to a central computer making it possible to do "online" registrations. Biomixer BM 323 has the same facilities but without the barcode reader and network option. Both units are powered by a mains adapter and have an internal rechargeable battery for stationary or mobile use.
5. Safety and Effectiveness, comparison to predicate device. The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

| Characteristic | Hemo-Matic® | Biomixer 330/323 scale/mixer for blood collection |
|---------------------------------------|--|---|
| Intended Use: | Blood Collecting, Weighing, and Monitoring | Same |
| Physical characteristics: | | |
| Size/weight | 435mm L x 175mm W x 125mm H; 3.5KG | 290mm L x 253mm W x 150mm H; 4.8KG |
| Energy Source: | 115/230 VAC or Internal Rechargeable battery | 115/230 VAC or Internal Rechargeable battery |
| User Interface | LCD | LCD |
| Data Registration | Bar Code Reader, (optional) | Bar Code Reader, (optional) |
| Computer Interface | Serial RS-232 | Serial RS-485 |
| Standards and Safety characteristics: | | |
| EMC | IEC 60601-1-2 | Same |
| Electrical safety: | IEC-60601, Class I, Type B | Same |

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of LJUNGBERG & KÖGEL AB that the Biomixer BM330 scale/mixer for blood collection is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate Device.