



HAEMOCELL plc

K960734

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510(K) SUMMARY

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- **Date** 31 January 1996

- **Device Identity**
 - Trade name Haemocell System 350
 - Proprietary name System 350 or S350
 - Common or usual name Autotransfusion Apparatus (per 21 CFR 868.5830)

1. **Legally Marketed Device**

Haemocell plc is proposing that the modified device which is the subject of this submission is equivalent to the Haemocell System 350 granted marketing clearance following submission of a 510(k) document (control number K914053B) and to the Baxter Medi-Vac ATS granted marketing clearance following the submission of a 510(k) document (control number K861677).

2. **Description of the Device**

2.1 **Device Function**

The Haemocell System 350 is a device designed for collecting and reinfusing a patient's own blood. It comprises an electromechanical system called a Filter Pump and a range of sterile, single use disposable products which when used in accordance with their operating instructions are safe and effective in various surgical procedures.

The single use disposables comprise:

Collection Sets: These are plastic, biocompatible reservoirs of 600 and 1200ml capacity which are used to contain blood suctioned from the patient during or after surgery. In both cases a regulated vacuum is applied to the collection reservoir by means of the hospital or a portable vacuum system. During surgery, a suction catheter provided with the collection reservoir is used to collect blood, whereas collection after surgery is effected by connecting a tube provided in the set to drains located at the surgical site by the surgeon.

Filter Sets: These are plastic, biocompatible, preassembled membrane filters connected to tubing and flexible containers. The sets are designed to locate on the electromechanical processing system in such a way that there is no contact between the processing system and the fluid content of the filter set, thus preserving the sterility of the fluid.

Reinfusion blood bags are located within either the collection set or filter set depending on the function of the set. The reinfusion bag is connected to the output of the filter set when processing is required and is used to reinfuse the processed blood when processing has been completed. Reinfusion is carried out under gravity, no pump operated or pressurised reinfusion is provided nor recommended.

The electromechanical hardware comprises:

- A mobile stand on which the Filter Pump is located for ease of movement and which provides the location for fluid reservoirs.
- A mains powered Filter Pump which when fitted with the correct disposables and set up according to the instructions for use will automatically process collected blood if required and selected by the operator. The Filter Pump is not required to be connected to the patient at any time in the procedure and can be operated by a circulating nurse or operating department assistant remote from the patient.

- Various reusable hardware components are used with the system, such as a vacuum canister for use with the 1200ml sterile collection reservoir to facilitate suction.

2.2 Principle of Operation

Following blood collection, and when processing is required, the Filter Pump controls the flow of fluid around the system by means of a peristaltic pump, pinch clamps, sensors, operator selection via a key-pad and an integral control system.

The purpose of the flow of fluid (principally blood) around the system is to create a flow across the surface of a membrane filter. The filter is designed to allow the liquid component of the fluid to pass through the membrane, whereas the particulate component (principally red blood cells) is maintained in the flow around the system. The membrane which effects the separation is a microporous material with a pore size smaller than the cells that are being conserved. Separation of the cells from the liquid creates a concentration of the cellular component and a reduction of the liquid component.

The separation is assisted by a proprietary process called vortex mixing which is produced by an oscillatory flow component being applied to the fluid flow by means of mechanical pistons acting on flexible diaphragms at the input and output ends of the filter.

This process results in the reduction of a major proportion of the contaminants in collected blood which is not required for reinfusion to the patient. The operator may select two different processes depending on their requirements and the Filter Pump will process the collected blood in accordance with the selected process.

The principle of this process is identical in the Haemocell System 350 as compared to the predicate device.

3. **Intended Use**

The Haemocell System 350 is an autologous transfusion system designed to collect blood during or after an elective or emergency surgical procedure, filter the blood, process as required by the physician, and reinfuse the autologous blood.

The Haemocell System 350 is designed to be used in accordance with the American Association of Blood Banks, Guidelines for Blood Salvage and Reinfusion in Surgery and Trauma (1993). No change to the intended use of the System 350 is proposed as compared to the predicate devices.

4. Technological Characteristics

4.1 Summary of Differences in Comparison to the Predicate Devices

4.1.1 Filter Pump

- Changes to the design of the Filter Pump to alter the peristaltic pump flowrate and ancillary features to ensure the effective operation of the system with the new pump flowrate.
- Introduction of an in-house manufactured power supply to reduce cost and accommodate changes to international regulatory requirements.
- Modifications to mechanical design to improve ease of use, reduce manufacturing cost and accommodate changes to international regulatory requirements.

4.1.2 Disposables

- Changes to the location of manufacture of the sterile disposables, including adoption of updated national and international standards for sterilisation by irradiation.
- Modifications to the design of the clamp used to meter anticoagulant during blood collection.
- Incorporation of a 1200ml collection system to offer a larger capacity collection reservoir.
- Introduction of a new filter set to accommodate the 1200ml collection set.
- Certain defined components have been added to the predicate System 350.

4.3 Summary of Similarities to the Predicate Devices

4.3.1 Filter Pump

- The system is identical in appearance and operator interface to the predicate device System 350.
- The principle of operation of the control system and function of the System 350 is identical to the predicate System 350.
- The principle of mechanical and electrical engineering construction of the System 350 and its accessories are identical to the predicate devices.

4.3.2 Disposables

- With the exception of certain defined components the materials used in the modified device are identical to those used in the predicate Haemocell 350. No change in biocompatibility has been detected.

- The components and materials used in the new Haemocell 1200ml collection set are identical to those used in the predicate 1200ml collection set.
- The principles of operation and design of collection, processing and reinfusion disposables are identical to those in the predicate devices.

5. **Non-Clinical Tests**

Throughout the period since the predicate device Haemocell System 350 has been marketed Haemocell has monitored the requirements of customers, distributors, suppliers and regulators and determined that a range of modifications have been applicable.

Depending on the change, appropriate testing has been planned, implemented and the results and conclusions analysed to ensure the continuity of Haemocell's assertion that the device is safe and effective. Three principal methods of test have been adopted to ensure adequate validation of proposed modifications; electromechanical type testing (BS EN 60601-1-1, BS EN 60601-1-2, UL 544), biocompatibility testing (Tripartite Biocompatibility Guidance for Medical Devices) and in vitro biological function testing.

The Haemocell System 350 has been shown to meet the requirements of the electromechanical testing as well as the predicate device; in material tests to give no indication of bio-incompatibility and in in vitro tests to perform in a substantially equivalent way to the predicate devices with clinically insignificant differences.

6. **Conclusion**

The modified Haemocell System 350 is substantially equivalent to the predicate devices in all areas of assessment: principle of operation, intended use, materials used, design and construction, compliance with standards, safety and effectiveness.

It is Haemocell's assertion that testing designed to establish the safety and effectiveness of the modified device, where changes have occurred, has shown that it performs as well as the predicate devices and the safety and effectiveness of the predicate devices has been maintained.