

6 – Special 510(k) Summary

SPECIAL 510(k) SUMMARY

6.1 ESTABLISHMENT INFORMATION

Company Name: **MAK-SYSTEM S.A.S International Group**
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6.2 DEVICE INFORMATION

The interface lab instruments are incorporated into blood bank stand alone application PROGESA.

Common Name: PROGESA
Proprietary Name: PROGESA
Classification Name: SOFTWARE, BLOOD BANK, STAND ALONE PRODUCTS

6.3 PREDICATE DEVICES

Manufacturer	Product	510(k) number
BBCS	BBCS Lab Interface Application V5.0L (BBCS Lab)	BK040087

6.4 DEVICE DESCRIPTION

The lab instruments interfaces incorporated into PROGESA application integrate the test results data into PROGESA.

The 510(k) cleared PROGESA is a modular, stand-alone software application, manufactured by MAK-SYSTEM, and designed to meet the needs of

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community blood banks or transfusion services. It is designed to assist the qualified and trained personnel to support the major operations within their facilities. PROGESA supports centralized multi-sites organization structure.

6.5 INTENDED USE

The following intended use is for 510(k) cleared PROGESA:

Blood Donor Operations

The primary purpose of PROGESA is to provide the automatic tools needed for daily blood donor operations, including, but not limited to the receipt and storage of data used in the determination of donor suitability, the collection and manufacture of blood and blood components. Specifically:

- Blood Drive Administration
- Tele-recruitment
- Donor Recruitment
- Mobile-team / Laptop
- Donor Administration
- Donation Administration
- Component Preparation
- Autologous Donors Management
- Laboratory Testing for donation & donor
- Component Validation and Labeling
- Quality Control of Product
- Look-back
- Donor Sample Storage
- Standard Operational Procedure Management
- Billing

This software application device is also intended to exert a controlling influence on the manufacture, labeling and release processes related to products intended for transfusion or further manufacture.

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Blood Transfusion Operations

Additionally, the software application is a device intended to undertake typical blood transfusion operations, including, but not limited to, the inventory, selection, testing, further manufacture, and the release and distribution of blood and blood products to appropriate transfusion services. Specifically:

- Quarantined Products
- Inventory Management, including Multiple-site Inventory
- Delivery/Shipping product
- Patient Sample Storage Management
- Look-back
- Patient Administration
- Patient Testing
- Laboratory Management for Patient
- Compatibility Testing
- Product Returns
- Transfusion Monitoring
- Inventory/Purchases Management
- Standard Operational Procedure Management
- Billing

These activities, for the transfusion environment, include among others:

- All Patient Testing
- Cross-match Activities
Remarks: Electronic cross-match function is only used as a double check, not for compatibility search.
- Transfusion Protocols
- Product Distribution

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Interfaces

PROGESA includes interfaces with LIMS, Lab Instrument that is intended to assist trained laboratory personnel in the transfer and integration of test results or data files to the PROGESA software.