

CSL Plasma

510(k) Summary

Date Prepared: December 11, 2019

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Trade Name: Anti-D Donor and Inventory Management System (ADIMS)
Classification Name: Establishment Computer Software and Accessories
Common Name: Blood Establishment Computer Software
Product Code: MMH
Regulation Number: 21CFR 864.9165

Predicate Device:

Device Classification Name: Establishment Computer Software and Accessories
510(k) Number: BK180240
Device Name: GDS Version 1.0 (Grifols Donation System)
Original Applicant: Biomat USA, Inc.
Product Code: MMH
Regulation Number: 21CFR 864.9165
Decision Date: November 5, 2018
Decision: Substantial equivalent (SE)
Type: Traditional

Device Description:

ADIMS is a stand-alone blood establishment computer software application (BECS) that provides for the management of plasma and whole blood donors for an RBC immunization program as well as the record and inventory management of immunogen red blood cells. The application is used to determine donor eligibility and release of the blood or blood component for transfusion as well as tracking the preparation of immunogen components (vials) for storage and distribution. Additionally, ADIMS allows for the tracking the recipient of transfused immunogen RBCs.

Indications for Use:

Intended Use for Predicate Device: Includes Special Plasma Programs: Management of specific collection and donor immunization programs.

Intended Use for ADIMS: ADIMS is indicated for the management of plasma and whole blood donors for an RBC immunization program as well as the record and inventory management of immunogen red blood cells by performing the following tasks:

- ADIMS is used to determine donor eligibility and release of the blood or blood component as suitable for transfusion;
- ADIMS is used to track the preparation of immunogen components (vials) for storage and distribution;
- ADIMS is used to track the recipient of transfused immunogen RBCs

Device Comparison Table:

Parameter/Character	Subject Device ADIMS Version	Predicate Device GDS Version 1.0, BK180240
Programming Language	Java version 1.8 utilizing Eclipse IDE	Java Development Technologies and PL/SQL
Database	Oracle 12.1.0.2	Oracle
Platform	Weblogic 12.2.1.3.0	Weblogic
OS	RedHat Enterprise Linux version 7.7 (Maipo)	RedHat
Web browser(s)	Internet Explorer 11	Internet explorer

Technological Characteristics:

As described in the table above, both ADIMS version 1.7 and GDS version 1.0 are based on an Oracle database, Java development technologies (including PL/SQL), running on a Weblogic server and RedHat platform designed for Internet explorer

Substantial Equivalence:

The proposed ADIMS application is substantially equivalent to the legally marketed GDS version 1.0 application in intended use, features and technological characteristics.

Both devices provide for the administration and maintenance of an RBC immunization program. Both devices are based on an Oracle database and use similar technology in operating system and hardware. The differences in technological characteristics and principles of operation between the two applications do not pose device safety or effectiveness concerns.

Non-Clinical Testing:

Based upon non-clinical testing, the ADIMS version 1.7 device was found to be safe for its intended use and is substantially equivalent to the predicate device in terms of intended use, functionality, technological characteristics as well as safety and effectiveness.