September 27, 2019

Fresenius Kabi AG
℅ Shane Sawall
Manager, Regulatory Affairs
Fresenius Kabi
Three Corporate Drive
Lake Zurich, Illinois 60047

Re: K192368
Trade/Device Name: CATSmart
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: August 29, 2019
Received: August 30, 2019

Dear Shane Sawall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192368

Device Name
CATSmart

Indications for Use *(Describe)*

The CATSmart System by Fresenius Kabi is an autotransfusion device indicated for the processing of autologous shed blood collected intraoperatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it can be used for perioperative separation of blood into Packed Red Cells (PRC), Plasma (PLS) and Platelet Rich Plasma (PRP).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Fresenius Kabi USA
Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

510(k) SUMMARY

Date Prepared

August 29, 2019

Owner/Operator and Contact Person

Owner/Operator	Owner/Operator #: 9027285 Fresenius Kabi AG Bad Homburg, GERMANY 61346
Contact Name: **Title:** **Address:** **Telephone:** **Fax:** **E-mail:**	Shane Sawall Manager, Regulatory Affairs Fresenius Kabi USA Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 USA 847-550-0702 847-550-2960 shane.sawall@fresenius-kabi.com
Official Correspondent: **Title:** **Address:** **Telephone:** **Fax:** **E-mail:**	Cheryl Roscher Vice President, Regulatory Affairs Fresenius Kabi USA Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 USA 847-550-7909 847-550-2960 cheryl.roscher@fresenius-kabi.com

Modified Device

Trade Name:	CATSmart
Common or Usual Name:	Automated Blood Processing Autotransfusion System
Product Code:	CAC
Classification Regulation:	21 CFR § 868.5830
Classification Name:	Apparatus, Autotransfusion
Regulation Description:	An autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.
Review Panel:	Anesthesiology
Device Class:	Class II

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed

Trade Name:	CATSmart
Common or Usual Name:	Automated Blood Processing Autotransfusion System
Product Code:	CAC
510(k) Number:	K180831
Date Cleared:	December 10, 2018
Device Class:	Class II

Device Description

The Fresenius Kabi CATSmart device is an intraoperative autotransfusion system for intra- and/or postoperative processing of blood lost through surgery or trauma.

The CATSmart device operates on the principle of a continuous flow centrifuge, comparable to continuous systems for hemapheresis which, for decades, have been widely used in blood banks.

In a typical CATSmart procedure, the shed blood, which is anticoagulated and collected in a sterile reservoir, is processed in a continuous washing process to obtain washed packed red cells for reinfusion to the patient. During this process all plasmatic and non-erythrocytic cellular components of the collected blood, and thus activated coagulation factors, products of fibrinolysis and cell trauma as well as the anticoagulant are removed. The packed red cells are collected in a reinfusion bag from which they can be reinfused to the patient via a transfusion set when needed.

In the Plasma Sequestration (PSQ) procedure, the patient's blood is separated into packed red cells (PRCs), plasma (PLS) and platelet rich plasma (PRP). The principle of separation during plasma sequestration is the same as it is for autotransfusion i.e. physical separation of cellular components in the centrifugal field based on the differences in density and particle size.

The system includes disposable sets and accessories previously cleared by FDA.

Indications for Use

The CATSmart System by Fresenius Kabi is an autotransfusion device indicated for the processing of autologous shed blood collected intraoperatively and postoperatively to obtain washed packed red blood cells for reinfusion. Additionally, it can be used for perioperative separation of blood into Packed Red Cells (PRC), Plasma (PLS) and Platelet Rich Plasma (PRP).

Technological Characteristics as Compared to the Predicate Device

The technological characteristics of the modified CATSmart device stay the same as the predicate CATSmart device. The only functional difference of the modified CATSmart device is that two additional wash factors have been included.

Performance Data

The performance of the two additional wash factors was tested by *in vitro* studies in comparison to the Smart Wash and Emergency Wash factors available in the predicate device. Results passed the acceptance criteria.

Software changes to add the other wash factors were verified with testing. Full system verification testing confirmed the changes did not impact other functional areas of the device.

Conclusion

The *in vitro* studies and the software verification demonstrate that the modified CATSmart device is substantially equivalent to the predicate device.