DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 16, 2016

Fresenius Kabi USA, LLC
% Barry Hicks
Manager, Regulatory Affairs
Three Corporate Drive
Lake Zurich, Illinois 60047

Re: K160735
Trade/Device Name: CATSmart
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: September 14, 2016
Received: September 16, 2016

Dear Barry Hicks:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160735

Device Name
CATSmart

Indications for Use *(Describe)*
The CATSmart (Continuous Autotransfusion System) device by Fresenius 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5: 510(k) Summary

1. Submitter

This 510(k) summary was created on 14 March 2016.

The 510(k) owner and contact person for this application is:

Name:	Barry G. Hicks
Position:	Manager, Regulatory Affairs
Company:	Fresenius Kabi USA, LLC.
Address	Three Corporate Drive Lake Zurich, IL 60047 USA
Phone:	847-550-7981
Fax:	847-550-2960
Email:	barry.hicks@fresenius-kabi.com

Establishment registration number: 3004548776

2. Device Name and Classification

Proprietary / Trade Name:	CATSmart
Common Name:	Automated Blood Processing Autotransfusion System
Classification Name:	Apparatus, Autotransfusion
Classification:	Class II per 21 CFR § 868.5830
Product Code	CAC
Panel	Anesthesiology

3. Predicate Device

This application is intended to demonstrate that the CATSmart Autotransfusion System, including its associated disposables, is substantially equivalent to the following predicate device:

510(k) number:	K960006
Proprietary / Trade Name:	C.A.T.S. Continuous Autotransfusion System
Common Name:	Automated Blood Processing Autotranfusion System
Classification Name:	Apparatus, Autotransfusion
Classification:	Class II per 21 CFR § 868.5830
Product Code:	CAC
Panel:	Cardiovascular
Manufacturer:	Fresenius AG, Frankfurter Str. 6-8, 66606 St. Wendel, Germany

The C.A.T.S. Autotransfusion System was modified with the addition of the following accessories under K984233 and K984586:

510(k) number:	K984233
Proprietary / Trade Name:	C.A.T.S AUTOTRANSFUSION ACCESSORIES, MODELS ATS SUCTION LINE, ATY Y-ADAPTER, AND ATO OXYGENATOR LINE
Common Name:	Automated Blood Processing Autotranfusion System
Classification Name:	Apparatus, Autotransfusion
Classification:	Class II per 21 CFR § 868.5830
Product Code:	CAC
Panel:	Cardiovascular
Manufacturer:	Fresenius AG, Frankfurter Str. 6-8, 66606 St. Wendel, Germany

510(k) number:	K984586
Proprietary / Trade Name:	FRESENIUS ATR40 AND ATR120 AUTOTRANSFUSION RESERVOIRS
Common Name:	Cardiovascular Surgical Devices
Classification Name:	Reservoir, Blood, Cardiopulmonary Bypass
Classification:	Class II per 21 CFR § 870.4400
Product Code:	DTN
Panel:	Cardiovascular
Manufacturer:	Fresenius AG, Frankfurter Str. 6-8, 66606 St. Wendel, Germany

4. Description

The product described in this document is the CATSmart (Continuous Autotransfusion System) including the disposables AT1, AT3, ATS, ATY, ATO, ATR40 and ATR120, ATV-70 and ATV-180, ATF40 and ATF120.

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.

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.

CATSmart is based on the predecessor products C.A.T.S. and C.A.T.S^{plus}, which have been in clinical use for almost 20 years. CATS was originally cleared in 1996. Following minor modifications it has been marketed as C.A.T.S^{plus} since 2005. CATSmart has as an additional technical feature: monitoring of the hematocrit value.

5. Intended Use

The CATSmart (Continuous Autotransfusion System) device 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.

6. Substantial Equivalence

Fresenius CATSmart is substantially equivalent to the predicate device system, with the following components.

a) The reusable autotransfusion device:
CATSmart is based on the predecessor products C.A.T.S. and C.A.T.S^{plus}, which have been in clinical use for almost 20 years. The main functions of CATSmart and the underlying methodology remained unchanged. In fact, the only functional difference of CATSmart compared to C.A.T.S./C.A.T.S^{plus} is the monitoring of the hematocrit value as an additional technical feature. Moreover, the main controller software was updated. The update includes the hematocrit function as a new item and usage of a touchscreen control instead of a keyboard. The software structure and the requirements remain unchanged compared to the C.A.T.S./C.A.T.S^{plus} software.

b) Disposables:
The predicate device C.A.T.S./C.A.T.S^{plus} system also includes the disposable blood processing chamber with all necessary tubing (called AT1) as described in the 510(k) submission K960006. The new disposable for the proposed device CATSmart is AT3. The only difference between AT3 and AT1 is the integration of a cuvette into the tubing for the hematocrit measurement. The AT1 disposable may also be used with CATSmart, but no hematocrit information will be displayed.

The following disposables have received prior 510(k) clearance, do not change in their usage with CATSmart, and are not further mentioned in this 510(k):

- ATS suction line (cleared under K984233),
- ATY Y-Adapter (cleared under K984233),
- ATO Oxygenator Line (cleared under K984233),
- ATR40 Autotransfusion Reservoir (cleared under K984586),
- ATR120 Autotransfusion Reservoir (cleared under K984586)

The following additional disposables are exempted from 510(k) submission, do not change with their usage with CATSmart, and are not further mentioned in this 510(k):

- ATV-70 and ATV-180 vacuum lines. These devices are classified as cardiopulmonary bypass accessory equipment and exempted according to 21 CFR § 870.4200.

Discussion of differences between CATSmart and the predicate device.
The only functional difference of CATSmart compared to C.A.T.S./C.A.T.S^{plus} is the monitoring of the hematocrit value as an additional technical feature. The hematocrit monitoring function of CATSmart is only used to monitor the wash process for informational purposes and is not intended for diagnostic or quality control purpose. As stated in the Operator's Manual, the hematocrit values given by the device are not a substitute for the hematocrit check on the product before it is reinfused in the patient. The sensors are not calibrated measuring instruments.

Conclusion:
Based on the identified characteristics it is claimed that the device is substantially equivalent to the predicate devices.

7. Performance testing

The performance of the CATSmart device was tested by *in vitro* blood quality studies in direct comparison to the predicate device C.A.T.S. (currently marketed as C.A.T.S^{plus}). All three wash programs (emergency wash program, low volume wash, smart wash) were tested. Overall it was judged that all validation tests were passed for all wash programs on the CATSmart device with the AT3 tubing set. A separate in vitro evaluation demonstrated that fat and heparin were almost completely removed from the processed blood. The electrical safety of the CATSmart device was tested according to the general requirements for basic safety and essential performance directive of IEC 60601-1-2:2007. Furthermore, vibration and shock resistance was tested as well as the durability.