February 11, 2021

Fresenius Kabi AG
% Cheryl Roscher
Vice President, Regulatory and Clinical Affairs
Fresenius Kabi
Three Corporate Drive
Lake Zurich, Illinois 60047

Re: K210089
Trade/Device Name: CATSmart
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: January 12, 2021
Received: January 13, 2021

Dear Cheryl Roscher:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210089

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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K210089

510(k) SUMMARY

Date Prepared

11th February 2021

Owner/Operator

Owner/Operator Owner/Operator #: 9027285
Fresenius Kabi AG
Bad Homburg, GERMANY 61346

Contact Person (include full address, phone and fax numbers)

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Device Trade Name

CATSmart

Common Name/Usual Name:

Automated Blood Processing Autotransfusion System

Classification Name

Class II per 21 CFR 868.5830 Apparatus, Autotransfusion

Product Code

CAC, Anesthesiology

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Legally Marketed Device Under Which Substantial Equivalence is Being Claimed

510(k) Number	K192368
Device Name	CATSmart
Common Name	Automated Blood Processing Autotransfusion System
Classification	Class II per 21CFR868.5830
Classification Name	Apparatus, Autotransfusion
Product Code	CAC
Review Panel	Cardiovascular
Manufacturer	Fresenius Kabi AG

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.

The system includes disposable sets and accessories previously cleared by FDA in respective 510(k)’s.

Indications for Use

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Technological Comparison as Compared to the Predicate Device

There is no change to CATsmart device design, materials, specifications, technological characteristics and function of the CATSmart disposable sets and accessories.

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Modification to the Existing Device

There is no design change to the FDA-cleared disposable sets and accessories. Manufacturing process and sterilization methods in the new site remain the same as previously cleared.

Performance Data

As part of the comprehensive sterility assurance program for the validation of this product, bioburden testing, verification of bacterial endotoxin and a performance qualification including biological indicators (BIs), temperature mapping, relative humidity, ethylene oxide concentration and residual testing was performed.

The sterilization validation results demonstrate that the sterilization activities performed do not impact the safety, effectiveness, quality, or fundamental technology of the CATSmart disposable sets and accessories.

Clinical Data

No clinical data was required to support the changes described in this submission.

Conclusion

The fundamental scientific technology, intended use, safety and effectiveness of the CATSmart Continuous Autotransfusion System including disposable sets and accessories remain the same. The validation activities performed in support of the change described in this application provide evidence that the proposed device is substantially equivalent to the predicate device.