August 22, 2018

Medtronic Perfusion Systems
Sue Fidler
Senior Regulatory Affairs Supervisor
7611 Northland Drive
Brooklyn Park, Minnesota 55428

Re: K181954
Trade/Device Name: autoLog IQ Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: July 17, 2018
Received: July 23, 2018

Dear Sue Fidler:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181954

Device Name
autoLog IQ™ Autotransfusion System

Indications for Use *(Describe)*
The autoLog IQ autotransfusion system and Medtronic wash kit are intended for use in the collection, concentration, washing, and reinfusion of autologous blood. Areas of application may include, but are not limited to, the following:
• Surgeries including general, cardiovascular, orthopedic, vascular, plastic/reconstructive, obstetric/gynecologic, and neurological
• Postoperative treatment areas

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5.0 510(k) Summary

Date Prepared: July 17, 2018

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

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Trade Name:	autoLog IQ Autotransfusion System
Common Name:	Autotransfusion apparatus
Product Code:	CAC
Regulation Number:	21 CFR 868.5830
Classification:	Class II
Classification Panel:	Anesthesiology
Special Controls:	To date, no special controls or performance standards have been established for these devices.

Name of Predicate Device:

autoLog Autotransfusion System, 510(k) K093535

Device Description

The autoLog IQ Autotransfusion System is used to collect autologous blood peri-operatively and post-operatively into a collection reservoir with an appropriate amount of anticoagulant. The system refers to the instrument (the subject of this submission); disposable devices are also required to operate the system: the Medtronic wash kit, collection reservoir, and suction line. This autologous blood is first filtered through the prefilter in the collection reservoir, and then processed by centrifugation, separating the red cells from the plasma. Contaminating debris is subsequently washed out by the introduction of normal saline in a wash cycle. The resulting packed red cells, suspended in normal saline, are pumped to a transfer bag, and may be reinfused to the patient. The autoLog IQ Autotransfusion System (also referred to as the "instrument" or the "system") is not patient contacting. However, the disposable devices needed to operate the system – the Medtronic wash kit, collection reservoir, suction line - are patient contacting, and are the same disposables used by the predicate autoLog Autotransfusion System device (K093535).

The collection and concentration/washing of patient blood are handled independently by the system. The collection process requires the installation of a disposable reservoir and the activation and use of the integrated vacuum pump, which is built into the system, or an external vacuum source. The system has an integrated internal regulator which ensures safe vacuum levels. The blood is aspirated through a disposable collection suction tip/cannula and disposable suction line to the reservoir. Anticoagulant is delivered at the cannula through the anticoagulant line.

The system's concentration/washing process requires the installation of the Medtronic wash kit and the activation and use of a pump, valve, and centrifuge. When the self-start switch registers a sufficient quantity of blood in the reservoir, the system automatically starts operation. The processing includes one cycle of filling the centrifuge bowl and concentrating the red cells (while transferring effluent waste to the waste bag), one cycle of washing the red cells with saline and one cycle of transferring the packed, washed red cells to the sterile holding bag. The pump pulls blood from the reservoir into the centrifuge bowl until the optical sensor detects a full bowl; then the roller pump stops and the wash solution is pumped into the packed red cell mass. After the washing cycle, the pump transfers the washed, packed red cells to the holding bag.

Medical personnel complete the final reinfusion of the collected and washed blood to the patient. Hospital personnel are instructed to dispose the waste bag (containing plasma waste, saline, and contaminating debris) in accordance with hospital guidelines.

Intended Use

The autoLog IQ autotransfusion system and Medtronic wash kit are intended for use in the collection, concentration, washing, and reinfusion of autologous blood. Areas of application may include, but are not limited to, the following:

- Surgeries including general, cardiovascular, orthopedic, vascular, plastic/reconstructive, obstetric/gynecologic, and neurological
- Postoperative treatment areas

Contraindications

The process of blood recovery is associated with few complications. The surgical team must consider the risks and relative contraindications of autotransfusion in any surgical procedure before proceeding with autotransfusion.

Comparison to Predicate Device

A comparison of the autoLog IQ Autotransfusion System to the predicate device (the autoLog Autotransfusion System) indicates the following similarities:

- Intended Use: The intended use is the same as predicate device.
- Design: The general device design is the same as the predicate device.
- Interaction with Disposables: The device uses the same disposable devices as the predicate device, for the same intended purpose, and with the same basic physical interfaces with the disposables as the predicate.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance is substantially equivalent to the predicate and/or reference device.

Summary of Testing

Testing has demonstrated that the autoLog IQ Autotransfusion System is substantially equivalent to the predicate.

The following tests were conducted:

Verification/Validation Test	Result
Software Unit, Integration, and System	Pass
Setup and Breakdown	Pass
Enclosure and Chassis	Pass
Cleanability	Pass
Unpackaged Transport	Pass
Vacuum	Pass
Roller Pump, Valve, and Weight Sensor	Pass
EE & Power Subsystem	Pass
Operating Conditions	Pass
Blood Washing Performance	Pass
Usability (Human Factors)	Pass
IEC 60601-1, IEC 60601-1-6, IEC 60529	Pass
IEC 60601-1-2	Pass
Packaging and Transport	Pass

Conclusion

The summary of the data, included in this submission, is sufficient to show that the autoLog IQ Autotransfusion System is substantially equivalent to the legally marketed predicate device, the autoLog Autotransfusion System.