May 21, 2020

Medtronic, Inc.
Sammie Joseph-Fredericks
Sr. Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K201068
Trade/Device Name: Affinity CP Centrifugal Blood Pump, Affinity CP Centrifugal Blood Pump with Balance Biosurface, Affinity CP Centrifugal Blood Pump with Cortiva BioActive Surface
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-Type Blood Pump
Regulatory Class: Class II
Product Code: KFM
Dated: April 21, 2020
Received: April 22, 2020

Dear Sammie Joseph-Fredericks:

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)*
K201068

Device Name
Affinity CP Centrifugal Blood Pump (Model AP40)

Indications for Use *(Describe)*
The Affinity CP centrifugal blood pump is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours). It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants). The Affinity CP centrifugal blood pump is driven by the external drive motor or the emergency handcrank. The Affinity CP centrifugal blood pump is intended for use with pump speed controllers approved by Medtronic or may be used with the Stöckert and Sorin centrifugal pump systems or the Sarns and Terumo centrifugal systems by attaching the Affinity CP adapter.

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
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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)*
K201068

Device Name
Affinity CP Centrifugal Blood Pump with Balance biosurface (Model BBAP40)

Indications for Use *(Describe)*
The Affinity CP centrifugal blood pump with Balance biosurface is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours). It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants). The Affinity CP centrifugal blood pump with Balance biosurface is driven by the external drive motor or the emergency handcrank. The Affinity CP centrifugal blood pump with Balance biosurface is intended for use with pump speed controllers approved by Medtronic or may be used with the Stöckert and Sorin centrifugal pump systems or the Sarns and Terumo centrifugal systems by attaching the Affinity CP adapter.

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)

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Indications for Use

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Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201068

Device Name
Affinity CP Centrifugal Blood Pump with Cortiva BioActive Surface (Model CBAP40)

Indications for Use *(Describe)*
The Affinity CP centrifugal blood pump with Cortiva BioActive Surface is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours). It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants). The Affinity CP centrifugal blood pump with Cortiva BioActive Surface is driven by the external drive motor or the emergency handcrank. The Affinity CP centrifugal blood pump with Cortiva BioActive Surface is intended for use with pump speed controllers approved by Medtronic or may be used with the Stöckert and Sorin centrifugal pump systems or the Sarns and Terumo centrifugal systems by attaching the Affinity CP adapter.

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)

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