April 12, 2019

Wendy Pinor
Principal Regulatory Affairs Specialist
7611 Northland Dr
Minneapolis, Minnesota 55428

Re: K183490
Trade/Device Name: Affinity NT™ Oxygenator (Model 511), Affinity® NT Oxygenator with Plasma Resistant Fiber (PRF) with Trillium™ Biosurface (Model 511T), Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541), Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541-R), Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T), Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T-R), Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT), Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT-R), Affinity NT™ Oxygenator with Cortiva™ BioActive Surface (Model CB511), Affinity NT™ Integrated Uncoated CVR/Oxygenator with Cortiva™ BioActive Surface (Model CB541), Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface (Model BB811), Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface (Model CB811), Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model BB841), and Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model CB841)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: January 16, 2019
Received: January 17, 2019

Dear Wendy Pinor:

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