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)*
K183490

Device Name
Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface (Model BB811)

Indications for Use *(Describe)*
The Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

The Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model BB841)

Indications for Use *(Describe)*

The Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

The Affinity Fusion™ Oxygenator with Integrated Arterial Filter with Balance™ Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery.

The Affinity Fusion™ Cardiotomy/Venous Reservoir with Balance™ Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum-assisted venous drainage (VAVD) procedures.

The Affinity Fusion™ Cardiotomy/Venous Reservoir with Balance™ Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface (Model CB811)

Indications for Use *(Describe)*
The Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

The Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model CB841)

Indications for Use *(Describe)*

The Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

The Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery.

The Affinity Fusion™ Cardiotomy/Venous Reservoir with Balance™ Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum-assisted venous drainage (VAVD) procedures.

The Affinity Fusion™ Cardiotomy/Venous Reservoir with Balance™ Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity NT™ Oxygenator (Model 511)

Indications for Use *(Describe)*
The Affinity NT™ Oxygenator is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

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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See PRA Statement below.

510(k) Number *(if known)*
K183490

Device Name
Affinity® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (PRF) with Trillium™ Biosurface (Model 511T)

Indications for Use *(Describe)*
The Affinity® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (PRF) with Trillium™ Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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See PRA Statement below.

510(k) Number *(if known)*
K183490

Device Name
Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541)

Indications for Use *(Describe)*
The Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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See PRA Statement below.

510(k) Number *(if known)*
K183490

Device Name
Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541-R)

Indications for Use *(Describe)*
The Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T)

Indications for Use *(Describe)*
The Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Plasma Resistant Fiber [PRF] Oxygenator with Trillium Biosurface) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T-R)

Indications for Use *(Describe)*
The Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Plasma Resistant Fiber [PRF] Oxygenator with Trillium Biosurface) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT)

Indications for Use *(Describe)*
The Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Plasma Resistant Fiber [PRF] Oxygenator with Trillium™ Biosurface) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT-R)

Indications for Use *(Describe)*
The Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Plasma Resistant Fiber [PRF] Oxygenator with Trillium™ Biosurface) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity NT™ Oxygenator with Cortiva™ BioActive Surface (Model CB511)

Indications for Use *(Describe)*
The Affinity NT™ Oxygenator with Cortiva™ BioActive Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

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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510(k) Number *(if known)*
K183490

Device Name
Affinity NT™ Integrated Uncoated CVR/Oxygenator with Cortiva™ BioActive Surface (Model CB541)

Indications for Use *(Describe)*
The Affinity NT™ Integrated Uncoated CVR/Oxygenator with Cortiva™ BioActive Surface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

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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