510(k) Summary

(in accordance with 21 CFR 807.92)

510(k) Number: K190690

I. Applicant Information

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Date Prepared: March 8, 2019

II. Subject Devices Identification

Proprietary Name:	**INSPIRE 7 Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**
Common/Usual Name:	INSPIRE 7
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II
Classification Panel:	Cardiovascular

Proprietary Name:	**INSPIRE 7M Hollow Fiber Oxygenator**
Common/Usual Name:	INSPIRE 7M
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II

Classification Panel:	Cardiovascular
Proprietary Name:	**INSPIRE 7 Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**
Common/Usual Name:	INSPIRE 7 Dual
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Devices

The **INSPIRE 7 Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir** is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	**K130433**
Proprietary Name:	**INSPIRE 8 Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**
Common/Usual Name:	INSPIRE 8
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II
Classification Panel:	Cardiovascular

The **INSPIRE 7M Hollow Fiber Oxygenator** device is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	**K180448**
Proprietary Name:	**INSPIRE 8M Hollow Fiber Oxygenator**
Common/Usual Name:	INSPIRE 8M
Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II

The **INSPIRE 7 Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir** device is substantially equivalent to the following cleared predicate device. Both models have the same fundamental scientific technology and intended use:

510(k) Number:	**K121229**
Proprietary Name:	**INSPIRE 8 Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**
Common/Usual Name:	INSPIRE 8 Dual

Classification Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II

IV. Devices Description

The intended use of the three subject devices is identical to the intended use of the three respective predicates devices.

The devices are used during cardiopulmonary bypass surgery to remove carbon dioxide, provide oxygenation and control blood temperature. They consist of the following main components:

- a **heat exchanger** consisting of a bundle of polyurethane hollow fibers that are wound on a cylindrical core;
- an **oxygenating module** element made of a coiled bundle of polypropylene microporous hollow fibers rolled on the heat exchanger sub assembly.
- a hardshell venous/cardiotomy reservoir to collect, filter, and send venous blood and suction blood to the oxygenator (only models INSPIRE 8/8DUAL and INSPIRE 7/7DUAL).

The **heat exchanger** consists of a bundle of polyurethane hollow fibers rolled on a cylindrical core. The heat transfer is obtained through the flow of water inside the fibers and the flow of blood outside them. The heat exchanger is inserted in the gas exchanger and surrounded by the **oxygenating module** element, which is constructed of a coiled bundle of polypropylene microporous hollow fibers rolled on the heat exchanger sub assembly. The blood path is around the outside of the fibers, while the gas path is through the lumen of the fibers. In the versions 8/8DUAL and 7/7DUAL the oxygenator module is integrated with a **hardshell/venous reservoir** via a molded fitting joint.

The **hardshell/venous reservoir** is comprised of rigid polycarbonate housing. Venous and cardiotomy filtering systems are physically distinct to allow a good filtration efficiency of venous and suction blood (one filters venous blood, the other filters suction blood). The reservoir is provided with a vent/vacuum port together with an over-under valve that prevents excess of negative or positive pressure, avoiding implosion and over pressurization of the reservoir itself. The blood enters the reservoir through the cardiotomy section through the rotating turret equipped with 3/8”, 1/4” and female luer inlet connectors and through the venous inlet 1/2” connector provided with female luer connector. Both cardiotomy turret and venous inlet connectors can rotate 360°. The reservoir lid has also additional unfiltered luer ports.

The oxygenating module of all the INSPIRE oxygenators include a dedicated outlet with a one way valve that provides access to arterial blood throughout the procedure for cardioplegia, perfusion or blood concentration. The outlet is placed close to the arterial outlet of the oxygenator and opposite to the temperature probe port. Arterial and venous temperature probe sites are also

provided: the former is located close to the arterial blood outlet, while the latter is placed on the venous inlet of the reservoir. **Figure 7-1** shows the oxygenating modules with the visible ports identified.

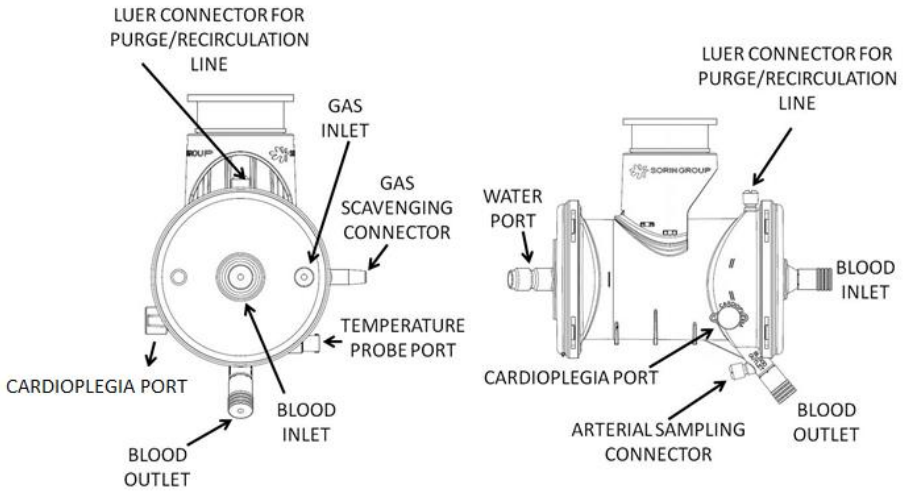

Figure 7-1: Oxygenating module integrated with heat exchanger

V. Indications for Use

All INSPIRE oxygenators – the three subject devices (i.e., the **INSPIRE 7 Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**, the **INSPIRE 7M Hollow Fiber Oxygenator** and the **INSPIRE 7 Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**), as well as the three predicate devices (i.e., the **INSPIRE 8 Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**, the **INSPIRE 8M Hollow Fiber Oxygenator** and the **INSPIRE 8 Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir**) – are intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. They all provide gas exchange support and blood temperature control and are intended to be used for 6 hours or less.

VI. Summary of Technical Characteristics

The technical characteristics of the subject INSPIRE oxygenators (i.e., 7, 7M and 7 Dual) are identical to those of the predicate INSPIRE oxygenators (i.e., 8, 8M and 8 Dual).

Blood aspirated from the patient and from the operating field (by gravity or by vacuum applied through an external source) enters the reservoir flowing through the venous and the cardiotomy filter, respectively. Blood is then filtered in order to remove solid particles, micro-aggregates, blood foam, and air bubbles. The blood volume in the reservoir is monitored by graduations on the hardshell.

Filtered blood is then pumped from the hardshell venous/cardiotomy reservoir to the venous inlet port of the gas oxygenating module. Incoming blood enters the heat exchange module, which is inserted inside the gas oxygenating module. The blood temperature is controlled by adjusting the temperature of the circulating water that flows inside the heat exchanger fibers, partially counter-flow in respect to blood flow direction.

Blood then flows into the gas module; gas flows through the interior of the hollow fibers and blood flows over the exterior of the hollow fibers. Arterial blood is collected in a collection chamber and flows back to the patient through the arterial outlet port.

Gas exchange takes place inside the gas module. A mixture of air and oxygen flows inside the gas exchanger fiber lumen, allowing oxygen exchange with blood across fiber walls due to an oxygen partial pressure differential between the gas and blood compartments.

Carbon dioxide, produced by patient metabolism, is removed from blood with the same exchange principle, passing from the blood to the gas compartment and exiting through the gas outlet port.

By regulating blood flow rate, gas flow rate, and percentage of oxygen in the gas mixture, it is possible to regulate oxygen delivery to the patient. Regulation of the patient body temperature allows modification of the patient metabolism, and change in patient oxygen requirement.

VII. Substantial Equivalence Discussion

The following tables compare the features of each subject INSPIRE device (i.e., 7, 7M and 7 Dual) with those of their respective predicates (i.e., 8, 8M and 8 Dual), with respect to indications for use, environment of use, intended use, limitations of use, principles of operation and main performance characteristics. More detailed information regarding the basis for the determination of substantial equivalence can be found in **Section 10** of this 510(k) submission.

The three subject devices have the same fundamental scientific technology and intended use as their respective predicate devices.