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)*

K190690

Device Name

INSPIRE 7 Dual Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir

Indications for Use *(Describe)*

The INSPIRE 7 Dual is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. The INSPIRE 7 Dual provides gas exchange support and blood temperature control and is intended to be used for 6 hours or less.

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
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Device Name

INSPIRE 7 Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir

Indications for Use *(Describe)*

The INSPIRE 7 is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. The INSPIRE 7 provides gas exchange support and blood temperature control and is intended to be used for 6 hours or less.

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)*

K190690

Device Name
INSPIRE 7M Hollow Fiber Oxygenator

Indications for Use *(Describe)*
The INSPIRE 7M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. The INSPIRE 7M provides gas exchange support and blood temperature control and is intended to be used for 6 hours or less.

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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