March 26, 2021

CardiacAssist, Inc.
Megan Walsh
Regulatory Affairs Manager
620 Alpha Drive, Suite 2
Pittsburgh, Pennsylvania 15238

Re: K202751
Trade/Device Name: TandemHeart Pump and Escort Controller
Regulation Number: 21 CFR 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure.
Regulatory Class: Class II
Product Code: QNR
Dated: February 19, 2021
Received: February 22, 2021

Dear Megan Walsh:

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,

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)*
K202751

Device Name
TandemHeart Pump and Escort Controller

Indications for Use *(Describe)*

The TandemHeart System is a centrifugal blood pump system intended to assist in circulation of the patient's blood when part of an extracorporeal circuit including physiologic gas exchange of the patient's blood in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

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.

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Section 5
510(k) Summary
510(k) Traditional

Date: 03/24/2021

Applicant

CardiacAssist, Inc. (dba TandemLife)
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Device

Trade/Proprietary Name:	TandemHeart Pump and Escort Controller
Common Name:	ECMO Pump and Controller
Classification Name:	Extracorporeal Circuit and Accessories for Long-Term Respiratory/Cardiopulmonary Failure (21 CFR 870.4100, Product Code QNR)

Primary Predicate Device: 81 FR 7451, Feb. 12, 2016

Secondary (Reference) Predicate Devices:

TandemHeart Pump (K991783)
Escort Controller (K061369)
TandemHeart Pump (K110493; Pump for use with oxygenator)

Device Description

The TandemHeart Pump is a low priming volume centrifugal blood pump with a dual chamber design. The upper chamber provides a conduit for the flow of blood; the lower chamber provides communication with the controller, a hydrodynamic bearing, cooling of the motor and local anticoagulation.

The TandemHeart Escort Controller provides the interface between pump and user, the power and electrical signals to drive the pump, and the infusate fluid to the lower chamber of the pump. It is a microprocessor-based electromechanical pump drive and infusion system designed to operate on standard AC current (100/240 VAC, 50/60 Hz) or on internal, rechargeable batteries for intra-hospital transport. The controller contains a backup motor control unit, and backup batteries.

Indication for Use

The TandemHeart System is a centrifugal blood pump system intended to assist in circulation of the patient's blood when part of an extracorporeal circuit including physiologic gas exchange of the patient's blood in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

Comparison of Technological Characteristics

The only modification to the currently-cleared devices is to the Indication for Use Statement. All other aspects of the subject devices are identical to the predicate devices.

Summary of Non-clinical Testing

Reliability
Hemolysis
Pressure/Flow Characteristics
Biocompatibility
Electrical Safety and EMC

Substantial Equivalence Comparison

Substantial equivalence analysis includes comparison to the special controls of FDA's Final Order, 81 FR 7451, Feb. 12, 2016, as well as comparison to the secondary (reference) predicate devices.

Special Controls

Special Control Number #1: ***The technological characteristics of the device must ensure that the geometry and design parameters are consistent with the intended use, and that the devices and accessories in the circuit are compatible.***

The technological characteristics of the device are consistent and compatible with the use of the device to pump the blood through an extracorporeal circuit.

Special Control Number #2: ***The devices and accessories in the circuit must be demonstrated to be biocompatible.***

The TandemHeart Pump meets all relevant biological endpoints per ISO10993-1 for a device in contact with circulating blood for a prolonged duration of use (24 hours to 30 days).

Special Control Number #3: ***Sterility and shelf-life testing must demonstrate the sterility of any patient-contacting devices and accessories in the circuit and the shelf life of these devices and accessories.***
Testing demonstrates the sterility of the subject device as provided and that it maintains its sterility, integrity, durability, and reliability over the stated shelf-life of the device.

Special Control Number #4: ***Non-clinical performance evaluation of the devices and accessories in the circuit must demonstrate substantial equivalence of the performance characteristics on the bench, mechanical integrity, electromagnetic compatibility (where applicable), software, durability, and reliability*****.**
Results of the reliability testing demonstrate the system achieves 90% reliability at 90% confidence for a 16-day mission.

Special Control Number #5: ***In vivo evaluation of the devices and accessories in the circuit must demonstrate their performance over the intended duration of use, including a detailed summary of the clinical evaluation pertinent to the use of the devices and accessories to demonstrate their effectiveness if a specific indication (patient population and/or condition) is identified*****.**

Section 13 of this submission includes new independent statistical analysis of data from the ELSO Registry, conducted by the Extracorporeal Life Support Organization. The propensity score analysis provided by the statistical group at ELSO clearly demonstrates the ability of TandemHeart Pump to provide assisted extracorporeal circulation of the patient's blood in adult patients. Moreover, the data demonstrates substantial equivalence to other devices used in the same manner. This analysis focused on the specific health risks appropriate to blood pumps that were outlined in the reclassification order, as recommended by the ELSO group in consultation with clinical experts in the field of ECLS. The specific health risks related to blood pumps and analyzed by ELSO include: pump failure; hemolysis; and thrombosis/clots.

The results of this independent propensity score analysis conducted by the ELSO group, in consultation with clinical experts in the ECLS field, showed that there was no difference in the primary or secondary outcomes in the TandemHeart pump and comparator group pumps. The analysis demonstrated that the subject device was substantially equivalent to similar devices used in the same manner for the endpoint associated with primary outcome/health risk of pump failure and secondary outcomes/health risks of hemolysis, thrombosis/thromboembolism (clots in circuit component).

The propensity score analysis demonstrates the TandemHeart Pump is substantially equivalent to the performance of other pumps when utilized in the application of ECMO as identified in the Final Order.

An earlier analysis was conducted (June 6, 2019) utilizing data from the ELSO Registry comparing the occurrence of complications reported with the TandemHeart Pump vs. comparator pumps ("non-TandemHeart pump").

A summary of the results of both the propensity score analysis dated February 4, 2021 (Section 5.1 Weighted Propensity Score Analysis) and the analysis dated June 6, 2019 (Section 5.2 TandemHeart Pump and Comparator Pumps Analysis) is provided below.

5.1 Weighted Propensity Score Analysis

A weighted propensity score model was used to compare the occurrence of nine Extracorporeal Membrane Oxygenation (ECMO)-related clinical outcomes between the Tandem Heart pump and other pumps used to assist in circulation of the patient's blood when part of an extracorporeal circuit including physiologic gas exchange of the patient's blood in adult patients. **5.1.1 Methods**

The primary analysis used 'overlap weights,' which induces balance between the distribution of predictors in the two treatment groups. The five outcomes of primary interest were pump failure, hemolysis, thrombosis or clots in circuit component, patient death within 24 hours of ECMO explant, and patient vital status at discharge. The four outcomes of secondary interest were central nervous system (CNS) hemorrhage, the use of renal replacement therapy (RRT) during ECMO, pulmonary hemorrhage, and a change in the EMCO circuit. Two sets of sensitivity analyses were performed. The first considered alternative propensity weighting methods: 'inverse probability weights' and 'matching weights'. A second sensitivity analysis combined runs into groups based upon using a common oxygenator and cannula, then stratifying the overlap-weighted results accordingly.

5.1.2 Results

The study period was January 2016 to October 2020. The study population consisted of 165 adult ECMO runs using the Tandem Heart pump and 3525 adult runs using a comparator pump at a center with at least one Tandem Heart run. Prior to weighting, the distribution of predictors between the two treatment groups exhibited broad imbalances. The distribution of estimated propensities for using the Tandem Heart pump were generally non-overlapping between the two groups. However, upon applying overlap weighting, the weighted distributions of predictors were well-balanced. The treatment effect of the Tandem Heart pump for pump failure was estimated to be -0.7% (95% CI -1.4%, 0.1%) relative to the treatment population, meaning that the Tandem Heart pump estimated to fail 0.7% less often in the overlap population relative to the comparator group.

The treatment effects of the Tandem Heart pump compared to the comparator for the other outcomes of interest in the overlap population were estimated to be:

- -3.6% (-14.2%, 7.2%) (hemolysis);
- -2.2% (95% CI -4.8%, 0.4%) (thrombosis/clots in the circuit component);
- 4.3% (95% CI -7.1%, 15.6%) (patient death within 24 hours of ECMO explant);
- 2.8% (95% CI -8.7%, 14.2%) (patient death at discharge);
- 4.5% (95% CI -0.01%, 9.0%) (CNS hemorrhage);
- 5.8% (95% CI -5.7%, 17.1%) (RRT during ECMO);
- 2.8% (95% CI -2.8%, 8.4%) (Pulmonary hemorrhage);
- 3.8% (95% CI -2.6%, 10.1%) (Circuit change).

The confidence intervals for these treatment effects all cover 0%, although narrowly in the case of CNS hemorrhage.

NOTE: The study is an enumerative study where all available ECMO data collected in the ELSO registry database that met the study criteria were analyzed. No hypothesis testing was prespecified and no multiplicity adjustment was made.

Alternative propensity weighting methods estimate the Tandem Heart pump treatment effect in different weighted populations. The first set of sensitivity analyses arrived at similar conclusions as the primary analyses, although some differences become “statistically significant” at a nominal 0.05 level. Specifically, using IPW, the estimated treatment effect for the outcome of pump failure was estimated to be -0.6% (95% CI -0.9%,-0.2%). Also using IPW, the estimated treatment effect for thrombosis/clots in the circuit was estimated to be -3.7% (95% CI -5.7%,-1.8%) and the estimated treatment effect with regard to RRT on ECMO is 28.9% (4.9%, 49.8%). Using matching weights, the treatment effect with regard to CNS hemorrhage is 4.3% (95% CI 0.1%, 8.4%). Although the magnitude of each effect estimate differs by the type of weight used, and the inverse-probability weighted analysis did not balance well the predictor distributions (was subject to high variability), the conclusions of the sensitivity analyses using different weighting methods are not substantively different than the primary analysis.

The other sensitivity analysis, which report separate results stratified by oxygenator and cannula type, were subject to substantially greater uncertainty in estimation, given the smaller sample size in each strata. Nonetheless, there were large treatment effects between some strata. Finally, the distribution of use of the Tandem Heart pump use across centers is noteworthy. A large proportion of the Tandem-Heart-pump-runs (nearly 50%) were at two of the 24 centers, and 15 centers had 3 or fewer Tandem-Heart-pump runs. The propensity score

model attempts to adjust for center-level associations. **Table 5-1: Weighted Outcome Models for Endpoints in Overlap Weighted Primary Analysis**

Endpoints	TandemHeart (n = 165)	Comparator (n = 3525)	Confidence Interval*
Pump Failure	0.2%	0.8%	(-1.4%,-0.1%)
Hemolysis	8.4%	11.9%	(-14.2%,7.2%)
Thrombosis/Clot in Circuit Component	1.5%	3.8%	(-4.8%0.4%)
Died Prior to 24 Hours post ECMO	44.9%	40.5%	(-7.1%,15.6%)
Discharged Dead from Hospital	56.9%	54.2%	(-8.7%,14.2%)
CNS Hemorrhage	7.5%	3.0%	(-0.01%,9.0%)
Renal Replacement Therapy	30.1%	24.3%	(-5.7%,17.1%)
Pulmonary Hemorrhage	10.7%	7.9%	(-2.8%,8.4%)
Circuit Change	7.7%	3.9%	(-2.6%,10.1%)

*The study is an enumerative study where all available ECMO data collected in the ELSO registry database that met the study criteria were analyzed. No hypothesis testing was prespecified and no multiplicity adjustment was made.

Table 5-2 Stratified Weighted Outcome Models using TandemHeart Pump with the most common membrane lung and one of the three most-common cannula brands used with that membrane lung.

Endpoints	Cannula Brand	N	Tandem-Heart	N	Com-parator	Confidence Interval*
Pump Failure	2	10	0.0%	331	1.1%	(-2.3%,0.2%)
	1	25	1.8%	121	0.0%	(-2.2%,5.9%)
	ProtekDuo	22	0.0%	76	2.4%	(-6.5%,1.6%)
Hemolysis	2	10	0.0%	331	0.9%	(-2.3%,0.4%)
	1	25	0.0%	121	2.2%	(-5.6%,1.3%)
	ProtekDuo	22	5.4%	76	1.5%	(-7.2%,14.9%)
Thrombosis/ Clot in Circuit	2	10	15.1%	331	2.5%	(-15.3%,38.5%)
	1	25	8.7%	121	11.9%	(-29.8%,23.9%)
	ProtekDuo	22	0.0%	76	4.5%	(-10.5%,1.6%)
Died prior to 24 hours post-ECMO	2	10	76.5%	331	28.7%	(-2.7%,78.8%)
	1	25	23.0%	121	32.5%	(-43.3%,26.6%)
	ProtekDuo	22	46.9%	76	53.1%	(-39.6%,28.6%)
Discharged Dead from Hospital	2	10	81.1%	331	55.7%	(-13.3%,57.4%)
	1	25	24.9%	121	34.5%	(-47.1%,30.9%)
	ProtekDuo	22	59.1%	76	56.1%	(-27,1%,32.6%)
CNS Hemorrhage	2	10	5.5%	331	1.9%	(-6.7%,13.9%)
	1	25	12.7%	121	0.1%	(4.8%,20.1%)
	ProtekDuo	22	4.8%	76	1.0%	(-5.3%,12.8%)
Renal Replacement Therapy	2	10	76.0%	331	18.4%	(-3.7%,87.4%)
	1	25	10.3%	121	21.7%	(-43.9%,23.7%)
	ProtekDuo	22	40.9%	76	21.7%	(-21.8%,54.4%)
Pulmonary Hemorrhage	2	10	66.4%	331	3.5%	(-27.5%,94.3%)
	1	25	0.0%	121	3.2%	(-7.2%,0.7%)
	ProtekDuo	22	5.5%	76	0.3%	(-4.9%,15.3%)
Circuit Change	2	10	0.0%	331	1.2%	(-2.6%,0.3%)
	1	25	0.9%	121	1.2%	(-3.4%,2.7%)
	ProtekDuo	22	5.5%	76	1.4%	(-6.1%,14.3%)

*The study is an enumerative study where all available ECMO data collected in the ELSO registry database that met the study criteria were analyzed. No hypothesis testing was prespecified and no multiplicity adjustment was made.

Table 5-3 Stratified Weighted Outcome Models using TandemHeart Pump with the most common membrane lung and one of the most-common modes of ECMO.

Endpoints	Mode of ECMO*	N	Tandem-Heart	N	Com-parator	Confidence Interval**
Pump Failure	VA, L/R FV, L/R FA	26	0.0%	704	0.7%	(-1.3%,-0.2%)
	VV, Dual Lumen	21	2.1%	113	0.0%	(-2.6%,6.8%)
	VVA or other mode	10	0.0%	40	0.5%	(-1.8%,0.7%)
	VV, Protek Duo 31	10	0.0%	37	5.7%	(-17.5%,6.3%)
Hemolysis	VA, L/R FV, L/R FA	26	0.0%	704	0.8%	(-1.8%,0.1%)
	VV, Dual Lumen	21	0.0%	113	2.2%	(-5.8%,1.4%)
	VVA or other mode	10	0.0%	40	0.0%	(-0.0%,0.0%)
	VV, Protek Duo 31	10	11.0%	37	0.6%	(-11.1%,30.9%)
Thrombosis/ Clot in Circuit	VA, L/R FV, L/R FA	26	6.6%	704	1.5%	(-8.6%,18.5%)
	VV, Dual Lumen	21	10.0%	113	11.9%	(-30.9%,27.4%)
	VVA or other mode	10	0.0%	40	0.8%	(-2.3%,0.7%)
	VV, Protek Duo 31	10	0.0%	37	0.2%	(-0.7%,0.3%)
Died prior to 24 hours post-ECMO	VA, L/R FV, L/R FA	26	47.0%	704	41.1%	(-23.7%,34.4%)
	VV, Dual Lumen	21	25.8%	113	32.0%	(-40.3%,29.4%)
	VVA or other mode	10	36.5%	40	40.5%	(-49.0%,42.7%)
	VV, Protek Duo 31	10	53.9%	37	17.6%	(-10.6%,70.0%)
Discharged Dead from Hospital	VA, L/R FV, L/R FA	26	48.5%	704	54.7%	(-36.4%,25.0%)
	VV, Dual Lumen	21	28.1%	113	34.1%	(-44.3%,34.3%)
	VVA or other mode	10	49.4%	40	87.2%	(-65.9%,-0.4%)
	VV, Protek Duo 31	10	78.6%	37	19.1%	(27.3%,79.8%)
CNS Hemorrhage	VA, L/R FV, L/R FA	26	1.6%	704	1.4%	(-3.4%,3.8%)
	VV, Dual Lumen	21	14.8%	113	0.1%	(5.1%,24.0%)
	VVA or other mode	10	0.0%	40	2.1%	(-5.9%,1.6%)
	VV, Protek Duo 31	10	9.7%	37	0.0%	(-6.1%,25.1%)
Renal Replacement Therapy	VA, L/R FV, L/R FA	26	24.4%	704	21.3%	(-37.3%,42.5%)
	VV, Dual Lumen	21	9.4%	113	21.6%	(-43.2%,21.4%)
	VVA or other mode	10	50.0%	40	14.2%	(-9.9%,69.1%)
	VV, Protek Duo 31	10	42.6%	37	4.3%	(5.4%,63.7%)
Pulmonary Hemorrhage	VA, L/R FV, L/R FA	26	19.3%	704	1.8%	(-22.0%,52.1%)
	VV, Dual Lumen	21	0.0%	113	2.2%	(-5.7%,1.3%)
	VVA or other mode	10	0.0%	40	3.5%	(-10.0%,3.1%)
	VV, Protek Duo 31	10	11.3%	37	0.2%	(-8.2%,29.6%)
Circuit Change	VA, L/R FV, L/R FA	26	0.0%	704	1.2%	(-2.2%,-0.3%)
	VV, Dual Lumen	21	1.0%	113	1.3%	(-3.5%,3.1%)
	VVA or other mode	10	0.0%	40	1.4%	(-3.3%,0.5%)
	VV, Protek Duo 31	10	11.3%	37	0.7%	(-8.5%,28.9%)

* ECMO Mode VA, L/R FV, L/R FA = Veno-Arterial ECMO, Left or Right Femoral Vein (drainage) and Left or Right Femoral Artery (reinfusion)

**The study is an enumerative study where all available ECMO data collected in the ELSO registry database that met the study criteria were analyzed. No hypothesis testing was prespecified and no multiplicity adjustment was made.

5.2 TandemHeart Pump and Comparator Pumps Analysis

All United States extracorporeal membrane oxygenation (ECMO) runs were extracted from the extracorporeal life support organization (ELSO) Registry with a record creation date between 1-Jan-2016 and 22-Jan-2019 for which the patient was at least 18 years old, the total hours on ECMO was less than 2160 (90 days), the support type was either 'Pulmonary' or 'Cardiac', and the pump used was either the Tandem Heart pump (ELSO pump ID 143) or a non-Tandem Heart centrifugal pump ["comparator pump"]). The patient population was additionally limited to those patients with exactly one recorded ECMO run, i.e. patients with multiple runs were excluded. This was done to decrease the potential for survivor bias.

5.2.1 Methods

Two stratification factors were applied. The first factor was pump used: Tandem Heart versus non-Tandem Heart (hereafter called 'Other centrifugal'). The second stratification factor was initial run mode: VA versus VV (all others modes excluded). Quoting from Conrad et al. (2018) [†]:

> VV support is the application of extracorporeal circulation primarily for respiratory support, in which the extracorporeal circuit drains blood from the venous system and reinfuses into the venous system. VV support operates in series with the heart and lungs, and does not provide bypass of these organs.
>
> VA support is the application of extracorporeal circulation primarily for cardiac or circulatory support, in which the extracorporeal circuit drains blood from the venous system and reinfuses into the arterial system. Without qualification, VA support refers to support that returns blood to the systemic arterial system, operating in parallel with and providing partial or complete bypass of, the heart and lungs.
>
> *†Conrad, Steven A, L Mikael Broman, Fabio S Taccone, Roberto Lorusso, Maximilian V Malfertheiner, Federico Pappalardo, Matteo Di Nardo, et al. 2018. "The Extracorporeal Life Support Organization Maastricht Treaty for Nomenclature in Extracorporeal Life Support. A Position Paper of the Extracorporeal Life Support Organization." American Journal of Respiratory and Critical Care Medicine 198 (4): 447–51*

Using these stratification factors, two types of analyses are presented in all tables. The first type of analysis stratifies by both pump and initial run mode. Runs having an initial mode of VA or VV fall into one of four categories: "Pump: Tandem Heart; VA", "Pump: Tandem Heart; VV", "Pump: Other centrifugal; VA", and "Pump: Other centrifugal; VV". Runs having an initial mode other than VA or VV, e.g. VVA, Other, Conversion, or Unknown, are excluded from this analysis.

The second type of analysis stratifies only by pump used, and there is no distinction between mode used, i.e. VA, VV, VVA, Other, Conversion, or Unknown modes are all included in this

analysis. Thus, every run falls into one of two categories, labeled “Pump: Tandem Heart; All modes” and “Pump: Other centrifugal; All modes”.

These six categories, four from one analysis and two from the other, comprise the six columns of results in each table in this report.

For all variables, appropriate summary statistics were calculated: for continuous variables, means, standard deviations [SDs], medians, interquartile ranges [IQRs], ranges, and for categorical variables, proportions and percentages.

5.2.2 Results

Results of the TandemHeart Pump and comparator pumps analysis for complications are provided in Table 5.4 below. ECLS complications, stratified by pump type (TandemHeart versus other centrifugal) and mode (VA, VV, or all modes). The second row, in grey, gives the proportion of runs with at least one complication reported from any category, the remaining grey rows indicate the proportion of runs with at least one complication reported from the named category of complications, and the remaining rows give the proportion of runs in which the specific complication was reported. All variables in this table are presence-only.

Table 5-4. Complications: TandemHeart Pump / Other Centrifugal Pumps

Complication	ECLS Code(s)	TandemHeart Pump			Other Centrifugal Pumps		
		VA	VV	All Modes	VA	VV	All Modes
Number runs		38	32	79	5214	3905	9801
≥1 of any type		63.2% (24)	75.0% (24)	67.1% (53)	58.7% (3061)	55.6% (2170)	58.8% (5761)
Mechanical		31.6% (12)	31.2% (10)	29.1% (23)	12.3% (643)	19.1% (744)	16.1% (1574)
Oxygenator failure	101	13.2% (5)	6.2% (2)	8.9% (7)	2.1% (112)	4.8% (186)	3.5% (339)
Pump failure	104	0.0% (0)	3.1% (1)	1.3% (1)	0.7% (39)	0.8% (33)	0.8% (78)
Cannula problems	131	2.6% (1)	3.1% (1)	2.5% (2)	2.8% (146)	4.6% (179)	3.7% (365)
Air in circuit	121	0.0% (0)	3.1% (1)	1.3% (1)	0.8% (44)	1.2% (47)	1.2% (114)
Circuit change	132	5.3% (2)	3.1% (1)	3.8% (3)	1.3% (68)	2.5% (97)	2.0% (199)
Emboli (clots or air)	133	0.0% (0)	0.0% (0)	0.0% (0)	0.1% (5)	0.1% (4)	0.1% (11)
Thrombosis / clots in circuit component	{111/112/113/115/116/134}	18.4% (7)	21.9% (7)	19.0% (15)	6.3% (326)	9.0% (350)	7.7% (757)
Hemorrhagic		31.6% (12)	15.6% (5)	24.1% (19)	25.4% (1325)	14.1% (552)	21.4% (2101)
Cannula site bleeding	{202/222/223}	21.1% (8)	6.2% (2)	15.2% (12)	13.2% (687)	5.6% (217)	10.4% (1024)
Surgical site bleeding	203	2.6% (1)	3.1% (1)	2.5% (2)	12.0% (626)	5.7% (222)	9.8% (962)
GI hemorrhage	201	13.2% (5)	9.4% (3)	10.1% (8)	4.2% (218)	4.5% (174)	4.4% (436)
Neurologic		10.5% (4)	9.4% (3)	8.9% (7)	7.8% (408)	5.3% (207)	7.0% (689)
CNS hemorrhage by US/CT/MRI	{322/323/324}	7.9% (3)	6.2% (2)	6.3% (5)	2.0% (105)	2.5% (99)	2.3% (230)
CNS Infarction by US/CT/MRI	321	2.6% (1)	0.0% (0)	1.3% (1)	4.1% (212)	1.4% (56)	3.1% (302)
Seizures	{311/312}	2.6% (1)	3.1% (1)	2.5% (2)	1.3% (67)	1.1% (42)	1.2% (121)

Complication	ECLS Code(s)	TandemHeart Pump			Other Centrifugal Pumps		
		VA	VV	All Modes	VA	VV	All Modes
Number runs		38	32	79	5214	3905	9801
Brain Death	301	0.0% (0)	0.0% (0)	0.0% (0)	1.7% (88)	1.0% (39)	1.5% (143)
Renal		44.7% (17)	43.8% (14)	41.8% (33)	37.5% (1954)	34.2% (1334)	37.1% (3634)
Creatinine 1.5 – 3.0	401	23.7% (9)	28.1% (9)	24.1% (19)	20.3% (1056)	16.5% (643)	19.0% (1866)
Creatinine > 3.0	402	5.3% (2)	6.2% (2)	6.3% (5)	9.7% (506)	7.8% (303)	9.2% (902)
Renal Replacement Therapy Required	{411/412/414/415}	36.8% (14)	34.4% (11)	34.2% (27)	24.6% (1281)	24.8% (970)	25.6% (2507)
Cardiovascular		2.6% (1)	15.6% (5)	7.6% (6)	5.4% (282)	4.9% (191)	5.7% (561)
CPR required	502	2.6% (1)	12.5% (4)	6.3% (5)	1.7% (91)	4.2% (164)	3.2% (312)
Tamponade (blood)	541	0.0% (0)	6.2% (2)	2.5% (2)	3.7% (192)	0.9% (36)	2.7% (264)
Tamponade (not blood)	{542/543/544}	0.0% (0)	0.0% (0)	0.0% (0)	0.2% (10)	0.1% (2)	0.2% (16)
Pulmonary		13.2%(5)	18.8% (6)	13.9% (11)	3.0% (158)	8.3% (326)	5.6% (551)
Pneumothorax requiring treatment	601	2.6% (1)	12.5% (4)	6.3% (5)	1.4% (71)	5.5% (213)	3.3% (321)
Pulmonary hemorrhage	602	10.5% (4)	6.2% (2)	7.6% (6)	1.8% (94)	3.6% (140)	2.8% (270)
Metabolic							
Hemolysis	{211/822/823}	7.9% (3)	3.1% (1)	5.1% (4)	4.2% (219)	4.8% (188)	4.8% (473)
Patient Limb		0.0% (0)	3.1% (1)	1.3% (1)	3.7% (191)	0.6% (24)	2.6% (255)
Fasciotomy	903	0.0%(0)	3.1% (1)	1.3% (1)	3.4% (176)	0.5% (18)	2.3% (225)
Amputation	904	0.0% (0)	0.0% (0)	0.0% (0)	0.6% (31)	0.3% (10)	0.6% (55)

Column notes:
ECLS complication codes (elso.org)
'All modes' is defined as any of VA, VV, VVA, Other, Conversion, and Unknown

Special Control Number #6: ***Labeling must include a detailed summary of the non-clinical and in vivo evaluations pertinent to use of the devices and accessories in the circuit and adequate instructions with respect to anticoagulation, circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure*****.**
The Directions for Use contain the information detailed in this Special Control.

Predicate Devices

81 FR 7451, Feb. 12, 2016
TandemHeart Pump (K991783)
Escort Controller (K061369)
TandemHeart Pump (K110493; Pump for use with oxygenator)

Conclusion

The information included in this 510(k) notification demonstrates that the TandemHeart System (TandemHeart Pump and Escort Controller) is substantially equivalent to the "Predicate

Device" for assisted extracorporeal circulation of the patient's blood in adult patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.