DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 24, 2016

Novocor Medical Systems, Inc.
% Ms. Tammy Carrea
Regulatory Consultant (RegMatters, LLC)
2 Davis Drive
Durham, North Carolina 27709

Re: K153162
Trade/Device Name: Hypocore
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: NCX
Dated: May 20, 2016
Received: May 23, 2016

Dear Ms. Tammy Carrea:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153162

Device Name
Hypocore

Indications for Use *(Describe)*
Hypocore™ is a single-use device intended to cool sterile saline, lactated ringers and other comparable low viscosity inert fluids during intravenous administration where clinically indicated for reduction of patient temperature.

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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510(k) Summary
[In accordance with 21CFR 807.92]

Novocor Medical Systems, Inc.
Hypocore

1. Submitter / 510(k) Holder

Novocor Medical Systems, Inc.
2 Davis Drive
Durham, NC 27709

Contact Person: Tammy B. Carrea
RegMatters, LLC

Date Prepared: May 20, 2016

2. Device Identification

Common Name:	Thermal Regulating System
Trade Name:	Hypocore
Regulation Number:	21 CFR 870.5900
Regulation Description:	Cardiovascular therapeutic devices, Thermal regulating system
Regulation Medical Specialty:	Cardiovascular
Review Panel:	Neurology
Product Code:	NCX - system, hypothermia, intravenous, cooling
Device Class:	II

3. Predicate Device

CLASS	MANUFACTURER	510(K) NUMBER	DEVICE NAME/DESCRIPTION
II	Medivance	K080899	Arctic Blast Intravenous Fluid Chiller

4. Device Description

The Hypocore device is an inline chiller for IV (Intravenous) solutions that uses an endothermic reaction for cooling. The IV fluids enter the device through a Luer-lock connector on a standard IV tube, is cooled inside the device and exits through another Luer-lock connector on a longer section of IV tube.

During expected use, the device inlet is connected to an IV solution bag via an IV administration set, and its outlet is connected to an intravenous access port.

It is powered by an internal non-rechargeable battery. The device has a handle to turn the device on and off.

The entire device is disposable, single use and is provided pre-sterilized.

5. Indications for Use/Intended Use

Hypocore™ is a single-use device intended to cool sterile saline, lactated ringers and other comparable low viscosity inert fluids during intravenous administration where clinically indicated for reduction of patient temperature.

6. Comparison of Intended Use

The intended use of the Hypocore is essentially the same as the Medivance Arctic Blast Intravenous Fluid Chiller in K080899. The main difference is that the types of fluids intended for use with the device are specified within the intended use statement for the Hypocore device.

7. Comparison of Technological Characteristics

The principles of operation and operational characteristics are the same and include a means of heat exchange resulting in the transfer or removal of heat from IV fluids.

Both devices are designed to connect the device inlet to the outlet of a sterile IV administration set and the device outlet to an IV access port and as such have similar connector materials and luer designs. Both device designs utilize a sealed sterile tubing fluid path as a cooling chamber. In both devices the sterile IV fluid flows through the tubing which acts as a means to transfer/remove heat resulting in fluid cooling. Neither device designs utilize an external power supply and neither of the devices utilizes software or a temperature controller for operation.

Both devices are designed for use in emergency medical situations and are provided for use in ambulances or other emergency vehicles. Both devices are activated using an activation switch or button on the front module.

Both devices are used in a sterile state and provided pre-sterilized. Both devices are disposable, for single use.

The Hypocore device and predicate device are different in that the Hypocore device specifies slightly different performance specifications. The performance specifications of the Hypocore device are based on known published literature regarding IV fluid cooling for situations such as cardiac arrest. These differences in specifications do not present new issues of safety and effectiveness because the Hypocore has demonstrated that it achieves its stated performance specifications and performs similarly to the predicate device. Performance testing has demonstrated that the Hypocore device meets all stated performance criteria.

Furthermore the Hypocore device provides for a standardized means of cooling IV fluids compared to the current standard of care, which consists of applying external cooling to solution bags, such as placing the IV bag in a cooler with ice or ice packs or storing the solutions in a refrigerator. In the case of the Hypocore device, fluid chilling is performed in real time so that the fluid from an entire bag of solution is chilled continuously, assuring constant and more consistent cooling.

See Table 1 below for a comparison of technological features and performance specifications.

Table 1. Substantial Equivalence Comparison

Product Feature	**Predicate Device**	**Proposed Device**
	Medivance Artic Blast IV Fluid Chiller, K080899	**Novocor Hypocore Device**
Regulation Number	21 CFR 870.5900	Same
Product Code	NCX	Same
Intended Use	The Medivance Arctic Blast Intravenous Fluid Chiller is intended to cool sterile solutions during intravenous administration where clinically indicated for reduction of patient temperature.	Hypocore™ is a single-use device intended to cool sterile saline, lactated ringers and other comparable low viscosity inert fluids during intravenous administration where clinically indicated for reduction of patient temperature.
Principle of Operation	Heat Exchanger – Cooling achieved via an adsorption process to transfer/remove heat resulting in cooling	Heat Exchanger – Cooling achieved via an endothermic reaction to transfer/remove heat, resulting in cooling
Cooling Chamber	Length of tubing, material unknown	Length of tubing, material – 60" of stainless steel, 31" of DEHP-Free PVC IV tubing.
Cooling Chamber Fluid Contact	None, cooling chamber fully sealed, no contact with sterile fluid	Same
Materials of Construction	Materials similar to those used in manufacture of IV administration sets	Same
Cooling Fluid	Unknown	Solution of Ammonium nitrate and water
Inlet	Connected to sterile saline bag	Same
Outlet	Connected to standard IV set	Same
External Power Source	None	Same
Software Control	None	Same
Temperature Controller	None	Same
Activation Method	Button on the module	Same, Activation switch on front of module
Sterile Fluid Path	Sterile fluid path incorporated into heat exchanger	Same
Disposable, Single Use	Yes	Same
Pre-sterilized	Yes	Same
Time to Cool	< 60 Seconds	Less than two minutes
Level of Cooling Achieved	2 liters of fluid to 4-6°C	1 liter of fluid to an average of less than 11°C
Storage Temperature	Room temperature	Same

8. Performance Testing Summary

A series of performance tests were performed to demonstrate the ability of the Hypocore device to cool fluids under expected conditions of use using low and high infusion rates as well as challenging environmental conditions including elevated temperatures.

Usability tests were conducted for the Hypocore device in accordance with the FDA Draft Guidance "Applying Human Factors and Usability Engineering to Optimize Medical Device Design" from June 22, 2011.

Biocompatibility studies were performed in accordance with ISO 10993-1.

Sterilization studies were also performed in accordance with ANSI/AAMI/ISO 11135 to demonstrate that the Hypocore device is able to be ethylene oxide (EO) sterilized to a sterility assurance level of $1x10^{-6}$.

Transit testing and expiration dating/shelf life tests were also performed to validate the durability and shelf life of the sterile barrier and outer shipper packaging.

The Hypocore device was tested for medical electrical safety compliance in accordance with international IEC standards IEC 60601-1 and IEC 60601-1-2.

Any technological differences between the Hypocore and the predicate device have been mitigated via functional, simulated use/usability, and standards based safety testing. A summary of verification and validation testing used to support substantial equivalence with the predicate device is provided below in Table 2.

Thus the Hypocore device does not introduce any new issues of safety or effectiveness compared to the predicate device.

Table 2. Non-clinical Performance Test Summary

Test	Test Method Summary	Results
10 Minute Standard Device Performance – Level of cooling, fast flow	Purpose: determine cooling capabilities for fast flow of IV fluids. 1 Liter of room temperature IV fluid was flowed from a standard bag via an administration set through the device in 10 minutes in room temperature conditions at a rate of 100 ml/min at room temperature. The average output temperature was measured.	All samples met the average output temperature acceptance criteria (range = 6.9-7.8 °C). Test was used to demonstrate that the Hypocore device meets its stated acceptance criteria to cool 1 liter of fluid to an average temperature of <11°C (based on standard of care- refrigerated IV fluid bag) and is therefore substantially equivalent in cooling capacity using the fastest expected flow rate.
30 Minute Standard Device Performance – Level of cooling, slow flow	Purpose: determine cooling capabilities for slow flow of IV fluids. 1 Liter of room temperature IV fluid was flowed from a standard bag via an administration set through the device in 30 minutes in room temperature conditions at a flow rate of 33 ml/min at room temperature. The average output temperature was measured.	All samples met the average output temperature acceptance criteria (range = 6.1-8.5 °C). Test was used to demonstrate that the Hypocore device meets its stated acceptance criteria to cool 1 liter of fluid to an average temperature of <11°C (based on standard of care- refrigerated IV fluid bag) and is therefore substantially equivalent in cooling capacity using the slowest expected flow rate.
30 Minute Standard Device Performance – Time to achieve required cooling level	Purpose: determine time to cooling capabilities. 1 Liter of room temperature IV fluid was flowed from a standard bag via an administration set through the device in 30 minutes in room temperature conditions. The time to achieve the required temperature threshold was measured.	All samples met the acceptance criteria for the time required to achieve the stated acceptance criteria of less than 2 minutes (range = 46-60 sec). Test was used to demonstrate that the Hypocore device meets its stated acceptance criteria and is therefore substantially equivalent for the time required to achieve cooling i.e. the time required to achieve the needed temperature threshold.
Elevated Environmental Temperature Test	Purpose: demonstrate that the device performs as intended under elevated temperature conditions, simulating summer like conditions 1 Liter of room temperature fluid was flowed from a standard IV bag at a rate of 48 ml/min inside a 32°C environmental chamber.	All samples met the acceptance criteria to cool the IV fluids to less than 11°C when flowed at 48 ml/min in a 32°C environment. The average temperature of the exiting fluid ranged from 8.8-10.5 °C inside a 32°C chamber.
Flow Rate Test – Comparative flow rate of standard IV set with and without the Hypocore device in line	Purpose: demonstrate that the Hypocore device does not noticeably reduce the flow rate of IV fluid. 1 Liter IV bag was gravity flowed through an IV administration set into a 14 gauge IV catheter and the standard flow rate measured. Next the Hypocore device was inserted and the flow rate measured.	Acceptance criteria required that the flow rate reduction be less than 25% of the standard flow rate. All samples met the acceptance criteria (flow rate reduction ranged from 10.35-15.87%).
Tilt Test	Purpose: evaluate the ability of the portable device to perform as intended when not parallel to a surface, at a tilt	All samples met the acceptance criteria which required that the temperature of the exit fluid be less than that of the initial

	angle of +/- 45 degrees. Test conducted with a flow rate of 100 ml/min at both angles. Temperature of fluid exiting the IV outlet evaluated during the infusion of 1 liter at each angle.	fluid. The average environmental temperature ranged from 22.5-22.8°C. The output temperatures during the test ranged from 8.6-9.2°C at +45 degrees and 9.1-10.1°C at -45 degrees.
Activation Handle Force Test	Purpose: Demonstrate that the activation handle does not break if over rotated. A force of 21 lb-in was exerted on the handle and it was determined whether the handle withstood the torque without breaking.	The acceptance criteria was that the activation handle must withstand 20.36 lb which is 50% of the highest wrist strength for 21-30 year old males. All samples withstood the applied force and no sample devices broke.
Strap Performance Test	Purpose: Demonstrate that the Velcro strap performs as intended to secure the portable device during operation. Three tests were performed: (1) The Hypocore device was subjected to a force equal to its own weight, (2) The pressure exerted by the strap on a limb was measured, (3) The Hypocore device was dropped from 41.5 inches and the force on the outlet tubing was measured.	(1) All samples met the acceptance criteria which was that the devices must stay attached to the limb. (2) All samples met the acceptance criteria which was that the pressure of the strap must not exceed 200 mmHg, the minimum pressure required to create a bloodless field for upper extremity surgery (pressures ranged from 50-80 mmHg). (3) All test iterations met the acceptance criteria that the force of the device be less than 52.9 N which is the force required to pull out a taped IV catheter. (forces ranged from 14.0-27.0 N)
Biocompatibility (Cytotoxicity)	Purpose: evaluate the Fluid Path and Skin contacting components of the Hypocore device for potential cytotoxic effects, based on using an in vitro mammalian cell culture test. The study was conducted following the guidelines of ISO 10993-5.	Acceptance Criteria: Test results are non-cytotoxic with scores of 0, 1, or 2 per ISO 10993-5. Fluid Path Results: The test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test, since the grade was less than a grade 2 (mild reactivity). Skin Contact Results: The test article extract showed evidence of causing slight cell lysis or toxicity; however, the test article extract met the requirements of the test, since the grade was less than a grade 2.
Biocompatibility (Irritation)	Purpose: evaluate the Fluid Path and Skin Contact components of the Hypocore device for the potential to cause irritation, based on intracutaneous injection in rabbits. This study was conducted based on ISO 10993-10.	Acceptance Criteria: Test results are non-irritant with scores of 0-1 comparison between control and test sample reaction (ISO 10993-10). Fluid Path Results: The test article met the requirements of the test, since the difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the sodium chloride (SC) and sesame oil (SO) test article extracts, respectively Skin Contact Results: The test article met the requirements of the test, since the

		difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.1 for the SC and SO test article extracts, respectively.
Biocompatibility (Sensitization)	Purpose: evaluate the Fluid Path and Skin Contact components of the Hypocore device for the potential to cause delayed dermal contact sensitization, based on a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10.	Acceptance Criteria: Test results are non-sensitizer or mild sensitizer with a score of 0, non-sensitizer, or 1, mild sensitizer, based on comparison between control and test sample (ISO 10993-10) Fluid Path Results: The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test. Skin Contact Results: The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.
Biocompatibility (Pyrogenicity)	Purpose: evaluate the Fluid Path components of the Hypocore device for material mediated pyrogenicity in the rabbit. The test was conducted based on USP, General Chapter <151>, Pyrogen Test, as recommended in ISO 10993-11.	Acceptance Criteria: No single animal temperature rise of 0.5°C or more above its baseline temperature. Test Results: No single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total rise of the rabbits' temperature during 3 hours was 0.0°C. The test article was judged as non-pyrogenic.
Biocompatibility (Ethylene Oxide and Ethylene Chlorohydrin Testing)	Purpose: evaluate and confirm acceptable Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) levels post Ethylene Oxide sterilization.	Acceptance Criteria #1: EO residuals - <= 4mg and ECH residuals - <= 9mg. Test Results: EO and ECH levels were acceptable on Day 1. Acceptance Criteria #2: The tolerable contact limits (TCL) for EO and ECH shall not exceed 10 µg/cm2 and 5 mg/cm2, respectively, or the device shall have negligible irritation as specified in ISO 10993-10. Test Results: The Hypocore device exhibited no irritation as demonstrated within biocompatibility irritation testing.
Biocompatibility (Partial Thromboplastin Time)	Purpose: evaluate the Fluid Path components of the Hypocore device for the potential to cause an effect on the coagulation cascade via the intrinsic coagulation pathway. The study was conducted in accordance to ASTM F2382.	Acceptance Criteria: test result clotting time > 50% of the negative control per ASTM F2382. Fluid Path Results: The plasma exposed to the test article had an overall average clotting time of 235.9 seconds, which represented 79.9% of the negative control. The test article was considered a minimal activator, and therefore, met the requirements of the test.

Biocompatibility (Acute Systemic Toxicity)	Purpose: evaluate the Fluid Path components of the Hypocore device for the potential to cause acute systemic toxicity in mice. This study was conducted based on ISO 10993-11.	Acceptance Criteria: reference ISO 10993-11 (Section 5.3). Fluid Path Results: There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.
Biocompatibility (Hemocompatibility)	Purpose: evaluate the Fluid Path components of the Hypocore device for the potential to cause hemolysis. This study was conducted based on ASTM F756 and ISO 10993-4.	Acceptance Criteria: Reference ISO 10993-4. Fluid Path Results: The hemolytic index for the test article in direct contact with blood was 2.0%, and the hemolytic index for the test article extract was 0.8%. The test article in direct contact with blood was slightly hemolytic and the test article extract was non-hemolytic.
Sterilization	Testing to establish a $1x10^{-6}$ SAL using ethylene oxide per ISO 11135.	Testing demonstrated that the Hypocore device is suitable to pass the acceptance criteria of ISO 11135 therefore demonstrating substantial equivalence for sterilization compared to the predicate device.
Medical Electrical Safety	Testing in accordance with IEC 60601-1 and IEC 60601-1-2.	Testing demonstrated that the Hypocore device meets the acceptance criteria of IEC 60601-1 and IEC 60601-1-2 therefore demonstrating substantial equivalence to the predicate device with regard to electrical safety.
Human Factors Design Validation	Purpose: Verify that the device is safe for the intended use, users, and use environment including interaction with sterile IV bags and standard IV sets by the expected user population. Testing was conducted in accordance with standards IEC 62366: 2007 (First Edition) + A1: 2014, IEC 60601-1-6: 2007 (3rd Ed.) and the FDA Draft Guidance "Applying Human Factors and Usability Engineering to Medical Devices" from February 3rd, 2016. Users were asked to setup and use the device independently without access to directions for use in a simulated useenvironment.	All users safely completed all use tasks successfully. This testing was used to demonstrate substantial equivalence regarding device connectivity to standard sterile IV bags and IV administration sets.

9. Preclinical and/or Clinical Tests

No preclinical or clinical testing was required to demonstrate that the Hypocore device met performance specifications and intended use.

10. Conclusion

The Hypocore device has been shown to be equivalent to the predicate in terms of intended use and operational and design features. Any differences in technology have been tested and verified and do not raise any new issues of safety and effectiveness.

- Both the Hypocore and Arctic Blast have the same intended use. Both devices provide for real time, continuous cooling of IV solutions during intravenous administration.
- Both devices utilize the same principle of operation which is to cool IV fluids via heat exchange.
- The operational functions and design features of the two devices are the same. Both devices connect to IV administration sets and provide a sealed sterile tubing fluid path which acts as a heat exchanger to remove/transfer heat. The materials of construction for both devices are compatible with or similar to those used in IV administration sets.
- Both devices are provided pre-sterilized and are disposable, single use.
- Both devices have been tested for biocompatibility and medical electrical safety.
- The only difference between the two devices is the stated cooling specifications. The performance specifications for the Hypocore device are based on research which measured and derived the temperature and flow rate of fluids used to achieve IV fluid cooling.

The conclusion drawn from the test data is that the Hypocore device has a safety and effectiveness profile that is similar to the predicate device, performs similarly to the predicate device, meets its stated performance criteria, and has a design that is substantially equivalent to the predicate device. Thus the Hypocore device is considered substantially equivalent to the Medivance Arctic Blast (K080899) predicate device.