13 510K Summary

AUG 13 2008

510(K) SUMMARY FOR ALSIUS CORPORTATION'S SOLEX CATHETER MODEL SL2593

Submitter's Name, Address, Telephone Number, and Contact Person:

ALSIUS CORPORATION
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Contact: John Riolo
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Name of Device:

Solex Catheter Model SL2593

Common or Usual Name:

Central Venous Catheter (short term) and Thermal Regulating System.

Classification Name:

21 CFR 870.5900 System, hypothermia, intravenous, cooling

Predicate Device:

K030421 Alsius Fortius Catheter Kit Model FR-5093
Decision Date 10/23/2003
Decision Substantially equivalent (SE)

Indications for Use

The Solex Catheter Model SL2593, connected to an Alsius External Thermal Regulation System, is indicated for use:

- in cardiac surgery patients to achieve and or maintain normothermia during surgery and recovery/intensive care, and
- to induce, maintain and reverse mild hypothermia in neurosurgery patients in surgery and recovery/intensive care.

Technical Characteristics:

The SOLEX catheter is a multi lumen intravascular catheter. The catheter has two lumens that are used to circulate sterile saline to exchange heat with the central venous blood supply. When the heat exchange feature of the catheter is in use, heated/chilled saline is pumped through the heat exchange lumen, expanding the diameter of the distal portion of the catheter to a nominal 12.2 mm where the heating/cooling membranes interface with the patient's circulating blood. The inflow lumen/outflow

lumen forms a closed-loop system through which the heated/chilled saline circulates. The chilled saline is not infused into the patient.

Additional lumens of the Alsius Solex Catheter Model SL2593 consist of a standard guide wire lumen that can be used as a primary infusion lumen, and two additional infusion lumens within the shaft.

The Solex Catheter Model SL2593 is the same as the predicate device, the Fortius Model FR-5093, K030421, except that:

- It has a shorter length balloon which results in reduced heat exchange power. As a result it has a significantly shorter length (25 cm vs 50cm).
- It is labeled for insertion via the jugular vein whereas the Fortius is labeled for femoral insertion.
- It has two additional infusion lumens.

	FR-5093 **Predicate - K030421**	Solex SL2593 **NEW**
Saline Circuit	Same	
Tip Infusion Lumen	Same	
Mid shaft Infusion Lumen	✗	✓
Lower shaft Infusion Lumen	✗	✓
Length	50cm tip to manifold	25cm tip to manifold
Shaft Diameter	Same – 9.3 Fr	
Heat Exchange Balloon Material	Same Material (PET)	
Heat Exchange Balloon Construction	Serpentine Construction .080" OD PET	Serpentine Construction .067" OD PET

✓ =Yes, present in design, ✗ =No, not present in design

The Catheter blood contact surfaces are coated with Duraflo® Treatment, a heparin coating manufactured by Edwards Lifesciences Corporation.

The Alsius Catheters are supplied sterile for single-use only.

Principles of Operation:

The Alsius temperature control system automatically adjusts the temperature of the heater/chiller saline bath to achieve the patient target temperature that has previously been set by the attending physician. This is done via data from a temperature probe in the patient that interfaces with the temperature controller. This principle of operation is identical to currently marketed devices.

Summary of the Basis for Finding of Substantial Equivalence:

The indication statement and intended use is identical to the predicate device. The principle of operation is the same as the predicate device. The technical characteristics and materials used are very similar to the predicate device.

Conclusion

In summary, descriptive information and performance data demonstrate that the Alsius Solex Catheter Model SL2593 characteristics do not raise new questions of safety and effectiveness. Where appropriate, performance data demonstrate equivalence. The Solex Catheter Model SL2593 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2008

Alsius Corporation
% Mr. John Riolo
VP, RA/CA/QA
15770 Laguna Canyon Road, Suite 150
Irvine, California 92618

Re: K081936
Trade/Device Name: Alsius Solex Catheter Model SL2593
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: July 30, 2008
Received: July 31, 2008

Dear Mr. Riolo:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081936

Indications for Use

510(k) Number (if known): K08XXXX

Device Name: Alsius Solex Catheter Model SL2593

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081936

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