DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

The Smithworks Company
C/O Ms. Patricia A. Milbank
Regulatory Consultant
2615 102nd Avenue NE
Bellevue, Washington 98004

DEC 2 2 2006

Re: K060851
Trade/Device Name: The Smithworks Company IV Fluid Warmer, Product Line: Soft Sack iv Fluid Warmer, FloorMount iv Fluid Warmer, Pak 2 iv Fluid Warmer and Thermal Sack Pressure Infuser
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LGZ
Dated: November 28, 2006
Received: December 1, 2006

Dear Ms. Milbank:

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.

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Date: 2021.06.26 12:38:23 EEST
Reason: MoldSign Signature
Location: Moldova

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Steve A. Murphy MD for Chiu Lin, Ph.D.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 of 4

1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: The Soft Sack iv fluid warmer

Indications for Use:

The Soft Sack iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] of Anesthesiology, General Hospital
[illegible]ion Control, Dental Devices

[illegible] K060851

1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: The FloorMount iv fluid warmer

Indications for Use:

The FloorMount iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...Control, Dental Devices

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1 Indication(s) for Use Statement

510(k) Number: K060851

Device Name: The PAK2 iv fluid warmer

Indications for Use:

The PAK2 iv fluid warmer is indicated for the warming or thermal maintenance of intravenous fluids prior to administration. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in hospital, clinical and field environments.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila H Murphy for Chiu Lin, PhD

Anesthesiology, General Hospital, Infection Control, Dental Devices

K060851

Indication(s) for Use Statement

510(k) Number: K060851

Device Name: Thermal Sack Pressure Infuser

Indications for Use:

The Thermal Sack Pressure Infuser is a thermal maintenance device. It is intended for use as an accessory for use with iv fluid warmer devices to enhance the ability to deliver thermal normal iv fluids in the field, by insulating the bag and tubing. This device is intended for use with crystalloid fluids only, such as normal saline and ringers lactate. This device is intended to be used by healthcare professionals in clinical and field environments. This device has not been tested for pediatric use.

Prescription Use ____√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ________ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheila H. Murphy MD for Chiu S. Lin PhD

...Anesthesiology, General Hospital, ...Control, Dental Devices

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