DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Enginivity LLC
C/O Penelope H. Greco
Vice President
MedApprove, Incorporated
8 Gray Lodge Road
Kittery, Maine 03904

JAN 1 0 2017

Re: K060537
Trade/Device Name: Enginivity™ eFlow IV Fluid Warmer
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: May 24, 2006
Received: May 24, 2006

Dear Ms. Greco:

This letter corrects our substantially equivalent letter of June 8, 2006.

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 Parts 801 and 809); 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 Parts 801 and 809]), 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" (21CFR 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K060537

Device Name: **Enginivity eFlow™ IV Fluid Warmer**

Indications for Use:

The eFlow IV Fluid Warmer is indicated for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.

Contraindications of use: The eFlow Disposable, Model 200 is not for use with platelets or drugs.

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible] of Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices
[illegible] Number: K060537

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990, 21 CFR 807.87, 21 CFR 807.92, Format for Traditional and Abbreviated 510(k)s.

1. Name of Submitter, Contact Person and Date Summary Prepared:

Name:	Enginivity LLC.
Address:	9 Grapevine Avenue, Suite 2 Lexington, MA 02421
Phone: Fax:	781-862-7008 781-674-9663
Official Contact:	David Cassidy Executive Vice President
Date of Preparation:	February 27, 2006

2. Device Trade Name and Common Name:

Trade Name:	eFlow™ Model 100 IV Fluid Warmer
Common/Usual Name: Classification Name:	Sterile Fluid Path, in-line Blood Fluid Warmer Warmer, Thermal, Infusion Fluid

3. Product Code: LGZ

   Device Class: unclassified

4. Legally Marketed Equivalent Device Names:

   Substantial equivalence is claimed to Estill Medical Technologies' Thermal Angel, Model 200 cleared under 510(k) K012031 on July 26, 2001.

5. Performance Standards:

   ASTM F 2172-02 Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers.

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6. Description of the Device:

The Enginivity eFlow™ IV Fluid Warmer consists of a warming device and a single use disposable set. The warmer can be powered by either an AC power adapter supplied by Enginivity LLC or a12-30 volt DC source meeting the requirements listed in the operators' manual. The warmer will deliver infusate to a patient at a temperature of up to 40°C at flow rates of 1 ml/min to a maximum of 200 ml/min.

The sterile disposable cartridge consists of a plastic housing and biocompatible coated aluminum extrusion which when combined form an enclosed fluid path. Heat, generated by electrical resistance, is transferred from the warmer to the fluid through the extrusion. Standard Luer fittings at the input and output allow the connection of standard hospital IV lines to the enclosed fluid path.

7. Intended Use of the Device:

The Enginivity eFlow™ IV Fluid Warmer is intended for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.

8. Comparison of technological characteristics with Predicate Devices:

The Enginivity eFlow™ Fluid Warmer is substantially equivalent to Estill Medical Technologies' Thermal Angel, Model 200.

9. Discussion of Non-clinical Studies:

Results of studies conducted on sterilized eFlow™ Disposable Cartridges demonstrate the materials to be biocompatible for its intended use. In addition, performance data demonstrate the temperature accuracy of the device at different flow rates.

Laboratory evaluations have been conducted to evaluate the hemolytic effect of the eFlow IV Fluid warmer during flows ranging from 10 to 200 ml/min and stopped flow.

10. Conclusion:

Results of studies performed have demonstrated the safety and efficacy of Enginivity's eFlow™ IV Fluid Warmer and substantial equivalence to its predicate devices.