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

August 25, 2016

410 Medical Innovation, LLC
% Dawn Reilly-O'Dell
Principal Consultant
Full Circle Regulatory Consulting, LLC
201 West Main Street, Suite 305
Durham, North Carolina 27701

Re: K153731
Trade/Device Name: LifeFlow™ Rapid Infusion Device (LifeFlow™ Device)
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 22, 2016
Received: July 25, 2016

Dear Dawn Reilly-O'Dell:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

510(k) Number *(if known)*

K153731

Device Name

LifeFlow™ Rapid Infusion Device (LifeFlow™ Device)

Indications for Use *(Describe)*

The LifeFlow™ Rapid Infusion Device is an intravenous administration set with Handle intended for rapid* delivery of fluids from a container into a patient's vascular system. The device is intended to deliver only crystalloid and colloid resuscitative fluids. These devices may be used for any pediatric or adult patient population with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused and duration of therapy.

*Capable of rates greater than 150 mL/min through a 20G needle.

Type of Use *(Select one or both, as applicable)*

[X] 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

I. SUBMITTER [807.92(a)(1)]	410 Medical Innovation, LLC. 201 West Main St, Suite 207, Durham, NC 27701 Phone: (844) 410-0410 **Contact:** Galen Robertson, C.O.O. **Date Prepared:** August 22, 2016
II. DEVICE NAME [807.92(a)(2)]	**Trade:** LifeFlow™ Rapid Infusion Device (LifeFlow™ Device) **Common:** IV Administration Set with Hand Pump **Classification:** IV Administration Set (21 CFR 880.5440, Class II, Product Code FPA)
III. PREDICATE DEVICE [807.92(a)(3)]	IV Administration Set with Hand Pump (21 CFR 880.5440, Class II, Product Code FPA) B. Braun, Inc., K140838 This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION [807.92(A)(4)]

Each LifeFlow™ Rapid Infusion Device (LifeFlow™ Device) is a disposable, single-use device that includes an intravenous administration set (Tubing Set) and a Handle and is used to deliver up to 4 Liters of fluid from a container into a patient's vascular system rapidly through manual compression of the levered Handle.

The Tubing Set is sterile, compatible with standard IVs and IV fluid bags and comprised of various generic components, such as a check valve, tubing, syringe, bag spike, thumb clamp, Luer access device, and Luer connections. Each of the needleless components are 510(k) cleared.

The addition of a hand pressure pump, the Handle, provides the capability for rapidly delivering IV fluids. The end of the Tubing Set is placed into the Handle. The clear canopy, through which the graduations and contents of the syringe can be viewed during use, is closed. The Handle is manually compressed to actuate the syringe, which delivers fluid to the patient and then automatically refills when the Handle is released.

Use Environments: Ambulance, Emergency Room/Department, ICU

Duration of Use: Within 24 hours of starting initial fluid resuscitation

V. INDICATIONS FOR USE [807.92(A)(5)]

The LifeFlow™ Rapid Infusion Device is an intravenous administration set intended for rapid* delivery of fluids from a container into a patient's vascular system. The device is intended to deliver only crystalloid and colloid resuscitative fluids. These devices may be used for any pediatric or adult patient population with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused and duration of therapy.

**Capable of rates greater than 150 mL/min through a 20G needle.*

VI. Explanation of Differences in Indications for Use Compared to Predicate:

The indications for use for both subject and predicate devices are substantially equivalent. The differences include 4 minor wording modifications numbered and bolded in the table below; a description of each follows.

SUBJECT DEVICE	**PREDICATE DEVICE**
1. The **LifeFlow™ Rapid Infusion device is an** intravenous administration set	1. The **IV Administration Sets with Hand Pump are** intravenous administration sets
2. is intended for **rapid*** delivery of fluids from a container into a patient's vascular system. ***Capable of rates greater than 150 mL/min through a 20G needle.***	2. intended for delivery of fluids from a container into a patient's vascular system.
3. These devices may be used for any **pediatric or adult** patient population with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused and duration of therapy.	3. These devices may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.
4. The device is intended to deliver only crystalloid and colloid resuscitative fluids.	4. **When the hand pump is activated,** the device is intended to deliver only crystalloid and colloid resuscitative fluids.

1. The first modification reflects the differences in naming of the two devices.

2. The second modification is the addition of the word "rapid". This description of fluid delivery, although not included in the predicate's indications for use, is included in the

Device Description published in the predicate's 510(k) Summary. A definition of rapid flow rate has been added for clarity and is based upon performance testing of the subject device.

3. Both predicate and subject devices are indicated for use with any patient population as long as proper consideration has been given to adequacy of vascular anatomy, appropriateness of the solution being infused and duration of therapy. The subject wording further clarifies "any patient population".

4. It was unclear from the predicate indications for use if the statement "when the hand pump is activated" allows for the syringe and administration tubing to be used without the hand pump to deliver other drugs or fluids. Therefore, the statement was removed for clarity and to align with the supporting performance testing of the subject device.

These modifications do not change the intended use in comparison to the predicate device and do not affect the safety and effectiveness of the device when used as intended.

VII. TECHNOLOGICAL CHARACTERISTICS [807.92(A)(6)]

The LifeFlow™ Rapid Infusion Device has the same indication for use as the B. Braun IV Administration Sets with Hand Pump in that they are both indicated for infusion therapy for the delivery of fluids to any patient through an increased flow rate provided by use of a manually activated hand pump. In the case of the proposed device, this hand pump is a levered Handle; in the case of the B. Braun IV Administration Sets, this hand pump is a flexible cylindrical chamber. The tubing length of the predicate device could not be confirmed; however, measurements of simulated use environments supported that the tubing length of the LifeFlow Device is sufficient for its intended use environments and therefore substantially equivalent.

Substantial Equivalence Table

Technical Characteristics	**Subject LifeFlow Device**	**Predicate IV Administration Set with Hand Pump**	**Substantial Equivalence**
Manual hand pump	Yes	Yes	Equivalent
Resuscitative fluids	Crystalloid and colloid	Crystalloid and colloid	Equivalent
Sterile IV Administration Set	Yes	Yes	Equivalent
Single Use	Yes	Yes	Equivalent
Needle-free	Yes	Yes	Equivalent
Cannula/catheter connection	Male Luer	Male Luer	Equivalent

Technical Characteristics	Subject LifeFlow Device	Predicate IV Administration Set with Hand Pump	Substantial Equivalence
Fluid container connector	IV spike	IV spike	Equivalent
Prevents backflow with dual-check valve	Yes	Yes	Equivalent
Injection site / Luer access device	Yes	Yes	Equivalent
Tubing set length	70 in. (50.8 cm) (approx.)	Similar	Functionally Equivalent
Rapid fluid delivery	Yes (flow rates > 150 mL/min)	Yes	Equivalent

VIII. PERFORMANCE DATA [807.92(B)(1)]

The following FDA recognized performance standards and guidance were utilized in evaluating the functionality of the LifeFlow™ Device:

- ISO 594-1:1986, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements*
- ISO 594-2:1998, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings*
- ISO 8536-4:2010, *Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed*
- ISO 10993-1:2009, *Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process*
- ANSI/AAMI/ISO 11137-2:2013, *Sterilization of health care products — Radiation — Part 2: Requirements for development, validation, and routine control of a sterilization process for medical devices*
- AAMI/ANSI HE75:2009/(R)2013, *Human Factors Engineering - Design of Medical Devices*
- Guidance for Industry and FDA Staff – *Intravascular Administration Sets Premarket Notification Submissions [510(k)]*, July 11, 2008

Functional performance testing was completed with the proposed LifeFlow Device to demonstrate that the device performs as intended. Testing included reliability, pressure, tactile feel, flow rate evaluations and user validations. Results of testing evidence that the proposed device performs in a manner that is substantially equivalent to the predicate.

Biocompatibility

The materials of construction of the fully assembled LifeFlow Device's IV set were tested according to ISO 10093-1:2009, as recognized by FDA. Testing for cytotoxicity, sensitization, irritation, systemic toxicity, hemocompatibility and pyrogenicity (LAL and material mediated tests) was completed. Chemical characterization, including extractables and leachables studies, and subsequent toxicology risk assessment, were also conducted.

Biocompatibility test results verify that the LifeFlow Device materials of construction are safe for their clinical application.

Sterilization

The Handle is not sterile, but the IV set is gamma sterilized. Sterilization and shelf-life testing were completed according to the FDA recognized ANSI/AAMI/ISO 11137-2:2013, Sterilization of healthcare products - Radiation - Part 2: Establishing the Sterilization Dose, and ISO 11607, respectively.

IV. CONCLUSIONS [807.92(B)(3)]

Biocompatibility, sterilization and non-clinical functional testing support the safety of the device and demonstrate that the LifeFlow Device meets its intended performance requirements. Results documented in user validation confirm the LifeFlow Device is as safe and as effective as the predicate device currently marketed for the same intended use. Therefore, it can be concluded based on the nonclinical tests discussed above that the LifeFlow Device is substantially equivalent to the predicate device.