May 20, 2020

410 Medical, Inc.
℅ Danielle Besal
Principal Consultant
MRC Global
6075 Poplar Ave.
Memphis, Tennessee 38119

Re: K191362
Trade/Device Name: LifeFlow® Blood System
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: FPA
Dated: May 14, 2020
Received: May 15, 2020

Dear Danielle Besal:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Tina Kiang Ph.D.
Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191362

Device Name
LifeFlow® Blood System

Indications for Use *(Describe)*
The LifeFlow® Blood System is an intravenous administration set that is intended for the rapid* delivery of blood, blood components (red blood cells or plasma), and crystalloid and colloid resuscitative fluids from a container to a patient's vascular system. These devices may be used for any adult or pediatric patient, greater than 28 days old and greater than 3kg, with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused, and duration of therapy.

The delivery of blood products is intended for patients requiring volume replacement for hemorrhagic shock or life-threatening bleeding.

*Capable of rates greater than 100ml/min

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
LifeFlow® Blood System
K191362
May 19, 2020

Company:	410 Medical, Inc. 201 West Main St, Suite 207, Durham, NC 27701 Phone: (844) 435-5450
Establishment Registration:	3012969104
Primary Contact:	Danielle Besal Principal Consultant | MRC Global Phone: (901)827-8670
Trade Name:	LifeFlow® Blood System
Common Name:	IV Administration Set
Classification:	Class II
Regulation Number:	21 CFR 880.5440
Panel:	General Hospital
Product Code:	FPA
Predicate Device:	LifeFlow™ Rapid Infusion System (K153731)
Reference Device:	IV Administration Sets with 200µm Blood Filter (K143082)

Device Description:
The LifeFlow® Blood System is a single use, disposable, intravenous administration set that is intended to deliver blood, blood components (red blood cells or plasma), and IV fluids from a container to a patient's vascular system rapidly using a hand pump. The set includes the handle, syringe, and tubing. The blood tubing features two IV spikes with roller clamps, blood filter chamber, air chamber, force reduction tubing, and luer connector.

Indications for Use:
The LifeFlow® Blood System is an intravenous administration set that is intended for the rapid* delivery of blood, blood components (red blood cells or plasma), and crystalloid and colloid resuscitative fluids from a container to a patient's vascular system. These devices may be used for any adult or pediatric patient greater than 28 days old and greater than 3kg with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused, and duration of therapy.

The delivery of blood products is intended for patients requiring volume replacement for hemorrhagic shock or life-threatening bleeding.

*Capable of rates greater than 100ml/min

Technological Characteristics Summary:
The subject LifeFlow® Blood System is substantially equivalent to the predicate device: LifeFlow™ Rapid Infusion System. The subject device components are similar to the predicate in terms of intended use,

geometry, and materials. The handle and syringe components are identical to the predicate, while the tubing differs to accommodate delivery of blood and blood components (red blood cells or plasma). The table below provides a comparison of technological characteristics. The minor differences in technological characteristics do not raise new questions of safety or effectiveness.

	SUBJECT	**PREDICATE**	**REFERENCE**	**Discussion**
	LifeFlow® Blood System K191362	**LifeFlow™ Rapid Infusion Device (K153731)**	**IV Administration Sets with 200 µm Blood Filter (K143082)**	
Product Code	FPA	FPA	FPA	Identical
Intended Use	Administration of blood, blood components (red blood cells or plasma), & crystalloid and colloid resuscitative fluids	Administration of crystalloid and colloid resuscitative fluids	Administration of blood, blood components, & IV fluids	Difference in compatible fluids; however, use of the product remains identical to the predicate. Reference device is intended for use with blood and blood components.
Indications for Use	The LifeFlow® Blood System is an intravenous administration set that is intended for the rapid* delivery of blood, blood components (red blood cells or plasma), and crystalloid and colloid resuscitative fluids from a container to a patient's vascular system. These devices may be used for any adult or pediatric patient, greater than 28 days old and greater than 3kg, with consideration given to adequacy of vascular anatomy, appropriateness for the solution being infused, and duration of therapy.	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	The IV Administration Sets with 200µm Blood Filter are used to deliver blood, blood components, and IV fluids from a container to a patient's vascular system. When the hand pump component is activated, the device is intended to deliver blood, blood products and crystalloid and colloid resuscitative fluids. 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	Difference to the addition of blood and blood components as compatible fluids; however, the use of the product remains identical to the predicate. Identical to the subject device, the reference device is indicated for delivery of blood and blood components. Difference in quantified flow rate versus predicate; however, the indicated subject device flow rate is supported by performance testing. Both subject and predicate devices are indicated for similar patient populations. The subject device provides a more specific patient population than the predicate.

		The delivery of blood products is intended for patients requiring volume replacement for hemorrhagic shock or life-threatening bleeding. *Capable of rates greater than 100mL/min.	through a 20G needle.	the duration of therapy.	
Patient Population		Adults & pediatrics (greater than 28 days old and greater than 3kg)	Adults & pediatrics		Same as the predicate with additional clarification of pediatrics definition for subject device, which aligns with the patient populations evaluated in the subject device performance testing.
Uses		Single	Identical		Identical to predicate
Administration Method		Hand pump activation	Identical		Identical to predicate
Hand Pump Design		Handle actuates a syringe to deliver fluid, which automatically refills when handle is released	Identical		Identical to predicate
Biocompatibility		ISO 10993-1	ISO 10993-1		Identical to predicate
Sterilization Method		Gamma (tubing set only, handle is non-sterile)	Identical		Identical to predicate
Sterility Assurance Level (SAL)		10^{-6}	Identical		Identical to predicate
Components					
Blood Filter	**Material**	Polyamide	N/A	Polyamide	Difference from predicate due to subject compatibility with blood; however, similar to reference device. The minor difference in filter surface area versus the reference device does not raise different questions of safety or
	Pore Size	200µm		200µm	
	Surface Area	$40cm^2$		$60cm^2$	

					effectiveness as the subject filter design complies with ISO 1135-4 and was verified through bench testing.
Tubing	**Length**	84”	60”	85”	Identical diameters to predicate, increase in length for compatibility with blood (similar to reference device).
	ID	0.094-0.170”	0.094-0.170”	0.120” & 0.190”	
	Material	Non-DEHP PVC & TPE	Non-DEHP PVC	PVC	
Air Chamber (Air Check)		Yes	No		Difference due to addition of air chamber versus the predicate. Reference device has a drip chamber; whereas, the subject device air chamber will stop the flow of air if it enters the chamber; however, does not raise new questions of safety and effectiveness.
Force Reduction Tubing (Force Reducer)		Yes	No		Difference from predicate; however, does not raise new questions of safety or effectiveness and subject device has been verified to yield substantially equivalent performance to predicate and reference devices.
Spikes		2	1	2	Identical to predicate spikes, only difference is in quantity to allow use with two bags, which is the same as the reference device.
Clamps		2 roller clamps & 1 pinch clamp	1 pinch clamp	3 roller clamps	Difference due to subject device ability to connect to two IV bags, similar to the reference device. The pinch clamp component is

				identical to that of the predicate device Two roller clamps were added, which matches the 3 total clamps of the reference device. This minor change does not raise new questions of safety or effectiveness.
Dual check valve	Yes	Yes		Identical to predicate
Luer connector	Yes	Yes		Identical to predicate
Needleless access Y connector	Yes	Yes		Identical to predicate

Difference In Technology:

- Air chamber - The subject device contains an air chamber ('AirCheck™') to prevent air from being delivered to the patient. AirCheck™ is located on the inlet tubing and assists the user in stopping the infusion if air trapped in the fluid bag enters the tubing. If a significant amount of air (approximately 20mL) enters the tubing, the ball float within AirCheck™ descends and forms a seal at the bottom of the chamber ('activates'). This activation prevents the LifeFlow® syringe from refilling and the handle from moving further (which provides a tactile indication to the user), while causing the flow of fluid to cease. The AirCheck™ chamber may be squeezed to purge any small volume of air. Since the subject device design requires constant user engagement, it has the advantage of the user immediately observing any activation of AirCheck™.

- Force Reduction mechanism - The subject device's force reduction tubing, also known as the Force Reducer, allows for a more consistent flow of fluid through the IV catheter while the LifeFlow® Handle is cycled. The Force Reducer is a section of flexible tubing located in the outlet tubing that is designed to decrease the peak force applied by the user and reduce the peak pressure applied to fluid being infused. The Force Reducer is a passive mechanism that does not require conscious effort from the user to operate.

- Blood filter - The subject device blood chamber is a chamber on the inlet tubing whereby blood enters and passes through a filter before flowing through the remaining tubing for administration to the patient. The filter is made from polyamide with a 200µm pore size and 40cm^2 surface area. The filter is compliant to section 5.6 of ISO 1135-4:2015 regarding filters for blood and blood components.

Performance Testing Summary:

Bench testing has verified the performance of the subject device is substantially equivalent to the predicate device. This testing included:

- Design verification in compliance to the following FDA recognized standards:
    - 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 1135-4: 2015 - Transfusion equipment for medical use, Part 4: Transfusion sets for single use, gravity feed
- Mechanical Hemolysis in comparison to the reference device
- Functional testing included reliability**,** human packed red blood cell infusion capability**,** flow rate with LifeFlow® Handle activation
- Human Factors usability testing
- Guidance for Industry and FDA Staff – *Intravascular Administration Sets Premarket Notification Submissions [510(k)]*, July 11, 2008

Biocompatibility
A biocompatibility evaluation was completed per ISO 10993-1, which included testing for cytotoxicity, sensitization, irritation, material-mediated pyrogenicity, acute systemic toxicity, hemocompatibility, particulates, and risk assessment.

Sterilization
The LifeFlow® Handle is not sterile, but the tubing is gamma sterilized. Sterilization 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. Pyrogenicity (bacterial endotoxins), packaging, and shelf life testing were performed.

Substantial Equivalence Conclusions:
In conclusion, there are no changes in the use of the subject device compared to the predicate and the minor design changes do not raise new questions of safety and effectiveness; thus, the subject device is substantially equivalent to the predicate.