April 23, 2020

MediFirst Co., Ltd.
℅ Sanglok Lee
Manager
Wise Company Inc.
#303, 142, Gasan digital 1-ro
Geumcheon-gu, Seoul 08301
Republic of Korea

Re: K192230
Trade/Device Name: MF SAFECATH
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: March 23, 2020
Received: March 24, 2020

Dear Sanglok Lee:

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)*
K192230

Device Name
MF SAFECATH

Indications for Use *(Describe)*
MF SAFECATH, an intravascular catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

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- K192230

01. Date 21.4.2020

02. Applicant
Company name: MediFirst Co.,Ltd.
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03. Submission Correspondent
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04. Proposed Device Identification
Proprietary Name: MF SAFECATH
Common Name: Intravascular catheter
Device Class: Class II
Regulation Number:21 C.F.R. 880.5200
Product Code: FOZ
Device Classification Name: Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days

05. Indication for use
MF SAFECATH, an intravascular catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

06. Predicate devices
- Predicate Device
510(k) Number: K013800
Regulation Number:21 C.F.R. 880.5200
Device Name: BD Insyte Autoguard Intravascular Catheter
Manufacturer: Becton Dickinson Infusion Therapy Systems Inc.

07. Device Description
This medical device is a disposable intravascular tube catheter composed of cap, cannula, catheter tube, catheter hub, gasket, g-holder, cannula hub, plug, filter. This device has a passive needlestick safety feature that prevents the cannula from escaping forward during the use.
MF SAFECATH are available in 16G, 18G, 20G, 22G, and 24G and various lengths.

08. Technological Characteristics

Comparison of Proposed device and the Predicate

	SUBJECT DEVICE (Proposed device)		PREDICATE DEVICE	Comment
Indications for Use	MS SAFECATH, an intravascular catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.		An intravascular catheter is a device that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure, or administer fluids intravenously. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.	Same
Materials	**Component**	**Subject Device**	**Predicate Device**	
	Catheter Tubing	Polyurethane	BD Vialon polyurethane	Different Please see #1. discussion below
	Catheter Hub	Polycarbonate	Polypropylene	Different Please see #1. discussion below
	Metal Wedge	N/A	Stainless Steel	Different. Please see #1. discussion below
	Needle	Stainless Steel	Stainless Steel	Same
	Needle Hub	Polycarbonate	Propionate	Different Please see #1. discussion below
	Needle Cover	Polypropylene	Polypropylene	Same
	Vent Plug	Polypropylene with filter	Polypropylene with filter	Same
	Catheter Tipping Lubricant	Polydimethylsiloxane	Polydimethylsiloxane-based Lubricant	Different Please see #1. discussion below
	Catheter Lubricant	Polydimethylsiloxane	Polydimethylsiloxane-based Lubricant	Different Please see #1. discussion below
	Wedge	N/A	Polydimethylsiloxane-	Different.

	Lubricant		based Lubricant	Please see #1. discussion below
	Needle (Cannula) Lubricant	Polydimethylsiloxane	Polydimethylsiloxane-based Lubricant	Different Please see #1. discussion below
Safety mechanism	*Passive needle shielding *A needle shield passively covers the inner needle when the needle is withdrawn from the catheter *Whole length cannula including cannula tip is shielded		*Active needle shielding *A needle is moved back actively by spring when the button is pushed *Whole length cannula including cannula tip is shielded	Different Please see #2. discussion below
Flashback	When catheter and needle are properly placed inside vessel, flashback can be confirmed after blood flow through ditch on the cannula surface.		When catheter and needle are properly placed inside vessel, flashback can be confirmed after blood flow through ditch on the cannula surface.	Same
Physical / Mechanical Specifications	Catheter Diameters: 16G, 18G, 20G, 22G, 24G Catheter Lengths: 0.75”, 1.00”, 1.16”, 1.25”,1.77”, 1.88” Non-winged		Catheter Diameters: 14G, 16G, 18G, 20G, 22G, 24G Catheter Lengths: 0.56”, 0.75”, 1.00”, 1.16”, 1.77”, 1.88” Winged or Non-winged	Different

#1. Discussion: Compared to the predicate product, the MF SAFECATH product is composed of different materials than the predicate device. These differences do not raise new or different questions of safety or effectiveness because this difference is a minor design difference. The MF SAFECATH was tested according to the ISO 10993 series, which demonstrated the biological safety of the device.

#2. Discussion: The difference between the proposed device and the predicate device is an operation method of the needlestick safety function. The safety function of BD Insyte Autoguard is operated manually when the push-button is pushed. The safety function of MF SAFECATH is operated automatically when the catheter hub and the others are separated. The shield of MF SAFECATH is moved forward to cover the inner cannula. This difference does not raise new or different questions of safety or effectiveness compared to the predicate. Both MF SAFECATH and BD Insyte Autoguard are designed to be stored inside the shield when the safety function is activated. MF SAFECATH contains a passive safety feature that automatically activates as the needle is withdrawn from the catheter. In addition, the needle of the BD Insyte Autoguard is exposed before the push button is pressed, and the MF SAFECATH needle is located in the shield during all stages of use, which reduces the likelihood of needle stick injury. Also, the safety feature of MF SAFECATH has been tested in simulated clinical use test and demonstrated the safety function has been activated correctly.

09. Summary of Performance Tests

Performance

Bench tests were conducted to verify that the proposed device met all design specifications, performances as was Substantially Equivalent (SE) to the predicate device. Bench testing performed to evaluate the performance of the subject device (MF SAFECATH) in accordance with the standards below.

- ISO 23908:2011 “Sharps Injury protection- Requirements and test methods -Sharps protection features for single use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 10555-1:2013 “Intravascular catheter – Sterile and single-use catheter Part 1: General requirements”
- ISO 594-1:1986 “Conical fitting with 6% (Luer) taper for syringe, 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 10555-5:2013 “Intravascular catheter – Sterile and single-use catheter Part 5: Over-needle peripheral catheters”
- ISO 9626:2016 “Stainless steel needle tubing for the manufacture of medical devices – requirements and test methods”

Sterilization, Shelf Life and Packaging

The sterilization process established in process definition can be delivered effectively and reproducibility to the sterilization load:
- ISO11135:2014 “Sterilization of health-care products- Ethylene oxide- Requirements for the development, validation and routine control of a sterilization process for medical devices”
- ISO11138-1:2006 “Sterilization of health care products -Biological Indicator-Part 1 General requirements”
- ISO11138-2:2006 “Sterilization of health care products-Biological Indicator-Part 2: Biological indicator for ethylene oxide sterilization processes”
- ISO11737-1:2006 “Sterilization of medical devices -Microbiological methods- Part 1: Determination of a population of microorganisms on products”
- ISO10993-7:2008 “Biological evaluation of medical devices- Part 7-; Ethylene oxide sterilization residuals”
- ISO11607-1:2006 “Packaging for terminally sterilized medical devices -Part 1: Requirements for materials, sterile barrier system and packaging systems (including Amendment 1 (2014)
- ISO11607-2:2006 “Packaging for terminally sterilized medical devices- Part 2: Validation requirements for forming, sealing and assembly processes (Including Amendment 1 (2014)
- AAMI TIR28:2009/(R)2013: “Product adoption and process equivalence for ethylene oxide sterilization.”

Biocompatibility

Biocompatibility of the subject device was evaluated in accordance with ISO 10993-1: Biomedical Evaluation of medical devices- Part 1: Evaluation and testing within a risk management process. Cytotoxicity, sensitization, irritation, acute systemic toxicity, subacute/aubchronic toxicity, pyrogenicity, and hemocompatibility tests were conducted.
Particulate Testing USP 788

Real-time and accelerated aging stability testing was performed to support shelf life of MF SAFECATH.

Simulated Clinical Use Study

A simulated clinical use study was conducted to MF SAFECATH I.V Catheter in accordance with FDA's Guidance for Industry and Staff, Medical Devices with Sharps Injury Prevention Features, issued on August 9, 2005 and ISO 23908: 2011, Sharps injury protection-Requirements and test

methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling.

10. Substantially Equivalent Conclusion

Based on the indications for use, technological characteristics, and performance testing, the proposed device, MF SAFECATH Intravascular catheter is determined to be Substantially Equivalent (SE) to the predicate devices in respect of safety and effectiveness.