September 13, 2022

Woo Young Medical Co., Ltd.
% Dave Kim
President
MTech Group
7505 Fannin St. Ste 610
Houston, Texas 77054

Re: K210929
Trade/Device Name: MagiCath II
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: September 12, 2022
Received: September 12, 2022

Dear Dave Kim:

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,

David Wolloscheck, Ph.D.
For Payal Patel
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210929

Device Name
MagiCath II

Indications for Use *(Describe)*
MagiCath II 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 general 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.

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K210929

510(k) Summary

21 CFR Part §807.92

Date 510(k) summary prepared: **September 12, 2022**

I. Applicant

Company	Woo Young Medical Co., Ltd. 98, Sangsin 2-gil, Jincheon-eup, Jincheon-gun, Chungcheongbuk-do, Korea Tel.: +82 (43) 536 0291 / Fax.:+82 (43) 536 0290
Contact person	Jenny Cho / RA Team Manager jennycho@wooyoungmed.com

II. Submission Correspondent

Official Correspondent

Company	Dave Kim, MBA MTECH GROUP 7505 Fannin St. Suite 610 Houston TX 77054 Tel: 713-467-2607 Email: davekim@mtech-inc.net

III. Proposed Device Identification

Trade Name	MagiCath II
Common Name	Short-Term Less Than 30 Days Intravascular Therapeutic Catheter
Regulation Name	Intravascular catheter
Regulation Number	21 CFR §880.5200
Product Code	FOZ
Regulatory Class	Class II
510(k) Review Panel	General hospital

IV. Predicate Device

Trade Name	BD Insyte™ Autoguard™ Intravascular Catheter
510(k) Number	K013800
Regulation Number	21 CFR §880.5200
Product Code	FOZ
Regulatory Class	Class II
510(k) Review Panel	General hospital

V. Device Description

MagiCath II, safety IV catheter is inserted into the patient's blood vessel for short-term use to collect blood, monitor blood pressure, or inject drugs. It consists of an over-the-needle, catheter made of radiopaque polyurethane with a passive safety shielding mechanism that will engage upon needle removal from the patient in order to prevent accidental needlestick injuries. The device is available in 18, 20, 22 and 24-gauge catheter.

MagiCath II is designed to allow users handling the device with single-hand, using the MagiGrip. In the MagiGrip, a vent fitting to regulate blood flow is placed. The needle hub is equipped with a vent filter which suppresses blood leakage, so the flashback can be more visible.

VI. Indication for use

MagiCath II 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 the general patient population with consideration given to the adequacy of vascular anatomy and appropriateness of procedure.

VII. Comparison of technological characteristics with the predicate device

Technological characteristics of the subject device are substantially equivalent to the predicate device. The subject Safety IV Catheter MagiCath II achieves its intended use based on the same or similar technology and safety mechanism as the predicate device. The substantial equivalence comparison of the subject device to the predicate devices is provided in the table below.

	MagiCath II (K210929)	BD Insyte™ Autoguard™ (K013800)	**Comparison**
Indications for Use	MagiCath II 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 the general patient population with consideration given to the 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.	Similar

Materials	Catheter tube Polyurethane Catheter hub Polypropylene Catheter Wedge Stainless steel Needle Stainless steel Needle hub Polycarbonate Needle Cover Polypropylene Vent filter Polyethylene with filter Lubricant for needle & catheter Polydimethylsiloxane	Catheter tube BD Vialon polyurethane Catheter hub Polypropylene Catheter Wedge Stainless steel Needle Stainless steel Needle hub Propionate Needle Cover Polypropylene Vent filter Polypropylene with filter Lubricant for needle & catheter Polydimethylsiloxane-based Lubricant	Differences are discussed in Note 1
Safety mechanism	Passive _A needle shield passively covers the guide needle when needle is upright after being withdrawn from the catheter _Whole length cannula including the cannula tip is shielded	Active _A needle is moved back actively by spring when the button is pushed _Whole length cannula including the cannula tip is shielded	The difference is discussed in Note 2
Flashback	When the catheter and needle are properly placed inside the vessel, flashback can be confirmed after blood flow through ditch on the cannula surface.	When the catheter and needle are properly placed inside vessel, flashback can be confirmed after blood flow through ditch on the cannula surface.	Identical
Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
Shelf-life	3 years	3 years	Identical
Catheter specification	Catheter Diameters: 18G, 20G, 22G, 24G Catheter Lengths: 0.75”, 1.00”, 1.16”, 1.88” Non-winged	Catheter Diameters: 14G, 16G, 18G, 20G, 22G, 24G Catheter Lengths: 0.75”, 1.00”, 1.16”, 1.25”,1.77”, 1.88” Winged or Non-winged	The difference is discussed in Note 3

Note 1

MagiCath II is composed of different materials than the predicate device. These differences do not raise new or other questions of safety or effectiveness because all materials used in the subject device are widely used for the IV catheters and are considered minor differences. The biocompatibility was assessed in accordance with ISO10993 series to demonstrate the biological safety of the device.

Note 2

The difference between the subject device and the predicate device is the operation method of the needlestick safety function. The safety function of BD Insyte™ Autoguard™ is operated actively when the push-button is pushed. The safety function of MagiCath II is operated passively. The needle fully enters the shield when the device is placed upright after disconnecting from the catheter. As the needle enters the shield, it rotates 90 degrees along the specifically designed line inside Shield Bottom and connects with the Inners, and the needle is fully retracted within the housing of thedevice.

Even when turned upside down, the sharp prevention never is deactivated. These differences do not raise new or different questions of safety or effectiveness because the Safety IV catheters, including both subject and predicate device, are designed for the needle to be stored inside the shield when the safety function is activated in order to prevent accidental needlestick injuries. Performance testing per ISO 23908:2011 demonstrated that the safety mechanism feature performs as intended.

Note 3

The subject device has fewer models, and the diameter and lengths are within the predicate's configurations. And that these differences do not raise new or different questions of safety or effectiveness.

VIII. SAFETY & PERFORMANCE DATA

Bench testing was performed to ensure the safety and effectiveness of the MagiCath II, Safety IV Catheter. Verification testing conforming to the standards listed in this application demonstrate substantial equivalence to the predicate device. No new safety and effectiveness questions are raised with the testing performed. Therefore, the MagiCath II is substantially equivalent to the predicate device.

Performance

- 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 10555-1:2013, "Intravascular catheter – Sterile and single-use catheter Part 1: General requirements"
- 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."
- ISO 7864:2016, "Sterile hypodermic needles for single use - Requirements and testmethods"
- 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

- FDA Guidance for Medical Devices with Sharps Injury Prevention Features - Guidance for Industry and FDA Staff
- USP <788> Particulate Matter in Injections test

Biocompatibility testing

The biocompatibility evaluation for the MagiCath II was conducted in accordance with the International Standard ISO 10993-1, "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Testing included the following:

- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Sensitization
- ISO 10993-10 - Intracutaneous (Intradermal) Reactivity
- ISO 10993-11 - Acute Systemic Toxicity
- ISO 10993-11 - Material-Mediated Pyrogen
- ISO 10993-11 - Subacute/Subchronic Toxicity
- ISO 10993-3/ISO 10993-33 Genotoxicity (Bacterial reverse mutation & In Vitro Mammalian chromosomal aberration)
- ISO 10993-4/ASTM F756-17 - In Vitro Hemolysis Test by Direct Contact and Indirect Contact Methods
- ISO 10993-4/ASTM F2382-18 - In Vitro Partial Thromboplastin Time
- ISO 10993-4/ASTM F2888-19 - In Vitro Hemocompatibility Assessment by Evaluating Platelet Leukocyte Counts and ItsAdherence
- ISO 10993-4 - In Vitro SC5b-9 Complement Activation
- ISO 10993-6 - Implantation

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014, "Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices."

IX. CONCLUSIONS

Based on the Indications for Use, technological characteristics, and performance testing, the subject device, MagiCath II safety IV catheter, does not raise different questions of safety and effectiveness when compared to the predicate. Therefore, it is substantially equivalent to the predicate device.