March 25, 2022

Mediplus (India) Limited
Alka Goel
Director Marketing
1261-1262, M.I.E. Part B, Bahadurgarh-124507 Haryana (India)
Bahadurgarh, Haryana 124507
India

Re: K210037
Trade/Device Name: Pluski Safe 1 Safety IV Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: February 21, 2022
Received: February 23, 2022

Dear Alka Goel:

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,

Gang Peng 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)*
K210037

Device Name
Pluski Safe 1 Safety I.V. Catheter

Indications for Use *(Describe)*
Pluski Safe 1 Safety IV Catheter is Passive anti-needle stick device for venous or arterial access for the infusion of fluids, drugs, and/or blood components. 14 –22 gauge catheters may be used with power injectors for which the maximum pressure setting is 300 psi.

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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MEDIPLUS (INDIA) LIMITED

K210037 510k Summary

Preparation Date: March 25, 2022

- **Submitter's Name:** Mediplus (India) Limited
- **Address:** Plot No-1261-1262, M.I.E. Part B, Bahadurgarh-124507 Haryana (India)
- **Contact Person Name:** Mrs. Alka Goel
- **Title:** Director Marketing
- **Phone Number:** +91-9818269055

Proprietary Name:	Pluski Safe 1 Safety I.V. Catheter
Common or Usual Name:	Safety I.V Cannula
Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Product Code:	FOZ
Device Class:	II
Review Pane:	General Hospital
Regulation Number:	21 CFR 880.5200

Predicate Device:

Mediplus Device	Predicate Device
Pluski Safe 1 Safety IV Catheter (K 210037)	Introcan Safety IV Catheter(K020785)

Device Description:

Pluski Safe 1 Safety I.V. Catheter is a medical device used for inserting a catheter into a patient's body for purpose of delivery of fluids or drainage of fluids from the patient's body. The device is equipped with a safety feature intended to prevent needle stick injuries. This device is engineered to protect healthcare workers using it against accidental needle stick injury and exposure to parts of the device that have come in contact with patient's blood or other body fluids and have hence been potentially contaminated with infectious agents.
The device contains different parts like Needle, Needle cover, Catheter, Catheter holder, body, Cross clip safety & filterHub cover. Devices are available in winged and non-winged version.

These devices are sold in sterile form & are single use devices.

Device is available in below mentioned sizes

Sr. No	Gauge Size	Length of Catheter (mm)	Catheter OD (mm)	Color
1	14G	32	2.10	Orange
2	16G	32	1.80	Medium Grey
4	18G	45	1.30	Deep Green
5	20G	32	1.10	Pink
6	22G	25	0.90	Deep Blue
7	24G	19	0.70	Yellow

Indications for Use:

Pluski Safe 1 Safety IV Catheter is Passive anti-needle stick device for venous or arterial access for the infusion of fluid, drugs, and/or blood components. 14 –22 gauge catheters may be used with power injectors for which the maximum pressure setting is300 psi.

S. No.	Technological Characteristics	Proposed Device (Mediplus India Limited)	Predicate Device (B. Braun Medical) K020785	Remarks
1	**Product Code**	FOZ	FOZ	Same as predicate device
2	**Regulation Number**	21 CFR 880.5200	21 CFR 880.5200	Same as predicate device
3	**Device Class**	Class II	Class II	Same as predicate device
4	**Indications For Use**	Pluski Safe 1 Safety IV Catheter is Passive anti-stick device for venous or arterial access for the infusion of fluids, drugs, and/or blood products. 14-22 gauge catheters may be used with power injectors which the maximum pressure setting is 300 psi.	Passive anti-stick devices for venous or arterial access for the infusion of fluids, drugs, and/or blood components. 14-22 gauge catheters may be used for power injections for which the maximum pressure setting is 300 psi.	Same as predicate device
5	**Catheter Gauges**	14G-24G	14G-24G	Same as predicate device
6	**Needle Safety Feature**	YES	YES	Same as predicate device

7	**Sterilization**	By EO (ethylene oxide gas sterilization)	By EO (ethylene oxide gas sterilization)	Same as predicate device
8	**Shelf Life**	5 Years	5 Years	Same as predicate device
9	**Device Use**	Single use	Single use	Same as predicate device
10	**Radio detectable**	Yes	Yes	Same as predicate device
11	**Material**	Polypropylene, Stainless Steel, P.U.R, Poly Oxy Methylene, Polypropylene, Resin	Stainless Steel, P.U.R	Different Comment #1
12	**Packaging**	Form/Fill/Seal Blister Pack	Form/Fill/Seal Blister Pack	Same as predicate device

Difference #1 Materials

The materials of construction for subject and predicate device are different. Biocompatibility testing has been conducted with the subject device that demonstrate that there is no biological risk. This difference does not raise new or different questions of safety or effectiveness.

Performance Standards:

The device performance of Pluski Safe 1 Safety I.V. Catheter has been demonstrated against the following applicable standards:

- **ISO 10555-1** Intravascular catheters — Sterile and single-use catheters — Part 1: General Requirements
- **ISO 10555-5** Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters
- **ISO 80369-7:** Small-bore connectors for liquid and gases in healthcare applications- Part 7 Connectors for intravascular or Hypodermic Applications Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical Equipment — Part 1: General requirements
- **ISO 80369-20:** Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
- **ISO 23908:**2011: Sharps injury protection-Features for single-use hypodermic needles, introducers for catheters, and needles used for blood sampling

Biocompatibility Standards

In accordance with ISO 10993-1, the short-term intravascular catheter is classified as: Externally Communicating Device, Circulating Blood, Prolonged Contact (>24 hours to 30 days). The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity

- Subchronic/Chronic Systemic Toxicity
- Hemocompatibility (hemolysis direct/indirect)
- Complement Activation testing
- Prothrombin time/Activated partial thromboplastin time testing
- Pyrogenicity
- Particulate matter testing

Sterility, Shipping and Shelf-life

- Shelf life 5 years validated per ASTM F1980-16
- Package Integrity testing, conditioning, and simulated shipping per ASTM D4169/ISTA 2A
- Sterile Barrier Package Testing performed on the subject device:
    - Peel testing ASTM F88/F88M:15
    - Dye Penetration ASTM F1929-15
    - Visual Inspection ASTM F1886-F1886M-16

Conclusion:

- The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Pluski Safety 1 Safety IV Catheter is substantially equivalent to Introcan Safety IV Catheter with respect to indications for use, target population, treatment methods and technological characteristics.