October 29, 2020

MedSafety Solutions LLC
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K200425
Trade/Device Name: Female Luer Lock Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular administration set
Regulatory Class: Class II
Product Code: FPA
Dated: September 14, 2020
Received: September 16, 2020

Dear Prithul Bom:

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,

Payal Patel
for Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200425

Device Name
Female Luer Lock Cap

Indications for Use *(Describe)*
The Female Luer Lock Cap is indicated for use as a cap for male Luer fittings on medical devices such as manifolds, stopcocks or IV sets.

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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SECTION 5: 510(K) SUMMARY

510(K) SUMMARY: K200425

DATE PREPARED: 10/19/2020

OWNER:

MedSafety Solutions LLC
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IDENTIFICATION OF THE DEVICE:

Trade Name:	Female Luer Lock Cap
Common Name:	Female Luer Lock Cap
Classification Name:	IV Administration Set
Classification Panel:	80 General Hospital
Classification:	21 CRF 880.5440
Class:	Class II
Product Code:	FPA

Subject Device Model No: 75309

PREDICATE DEVICE(S):

Device:	Dual Luer Lock Cap
Company:	Baxter Healthcare Corporation
510(k) Number:	K101385
Clearance Date:	June 22, 2010

DESCRIPTION OF DEVICE:

The Female Luer Lock Cap is an individually packaged, sterile, single use disposable product used to cover male Luer fittings. Luer fittings are commonly used on IV administration products and accessories to provide universal compatibility and are well established in the market. Luer lock fittings are securely joined by means of a tabbed hub on the female fitting which screws into threads in a sleeve on the male fitting. The Female Luer Lock Cap is an injection molded, polyethylene component. Polyethylene material is durable, biologically inert, gamma stable, and used extensively in the medical device industry. The product is terminally gamma sterilized to a Sterility Assurance Level (SAL) of 10^{-6}.

The Female Luer Lock Cap is not associated with any specific medical condition. The user group consists of those involved in pharmacy compounding, mainly pharmacy

technicians and pharmacists, as well as health care professionals. Covering Luer fittings helps reduce the risk of touch contamination and medication leakage.

The basis for the premarket notification is a new device that has not been marketed previously by MedSafety Solutions. The Indications for Use, the basic design and function for the subject device are equivalent to the legally marketed predicate device.

INDICATIONS FOR USE:

The Female Luer Lock Cap is indicated for use as a cap for male Luer fittings on medical devices such as manifolds, stopcocks or IV sets.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The proposed device is substantially equivalent to Baxter Healthcare's current legally marketed device cleared under 510(k) premarket notification K101385 cleared June 22, 2010 given that the subject device has the same Indications for Use, basic design, and function as the predicate device.

The primary difference between the predicate device and the subject device is that the predicate has both male and female Luer connections whereas the subject device only has a male Luer lock connection.

The change in material from the predicate device from Polypropylene to Polyethylene does not raise new questions of safety or efficacy. Polypropylene and Polyethylene are both used extensively for medical products. Polyethylene was selected for the subject device because of its low moisture absorption, is biologically inert, gamma stable, is mechanically stable and the material's sustainability (i.e. recyclable). Performance testing of the subject device for the design and functional performance and biocompatibility assessment have demonstrated the subject device is substantially equivalent to the predicate device.

Table 5-1: Comparison of Technological Characteristics

Feature / Specification	***Predicate Device*** **Dual Luer Lock Cap K101385**	***Subject Device*** **Female Luer Lock Cap**	**Comparison**
Product Classification	Class II - FPA IV Administration Set	Class II - FPA IV Administration Set	Identical
Indications for Use	The Dual Luer Lock Cap is indicated for use as a cap for male or female Luer ports on medical devices such as manifolds, stopcocks or sets.	The Female Luer Lock Cap is indicated for use as a cap for male Luer fittings on medical devices such as manifolds, stopcocks or IV sets.	Substantially Equivalent - difference is the predicate has both male and female Luer connections whereas the subject device only has a

Feature / Specification	*Predicate Device* Dual Luer Lock Cap K101385	*Subject Device* Female Luer Lock Cap	Comparison
			male Luer lock connection
Sterile	Yes	Yes	Identical
Sterility Assurance Level	SAL of 10^{-6}	SAL of 10^{-6}	Identical
Single Use	Yes	Yes	Identical
Non-Pyrogenic	Yes	Yes	Identical
Materials	Injection molded, Polypropylene component Biocompatibility ISO 10993 • Cytotoxicity • Sensitization • Intracutaneous Reactivity/ Irritation • Systemic Toxicity • Hemo-compatibility • Material-Mediated Pyrogen • Subacute toxicity • Subchronic toxicity Material shelf-life ISO 594 • Ease of assembly ISO 80369-7 • Positive Pressure Liquid Leakage • Sub-atmospheric Pressure Air Leakage • Stress Cracking • Resistance to Separation from	Injection molded, Polypropylene component Biocompatibility ISO 10993 • Cytotoxicity • Sensitization • Intracutaneous Reactivity/ Irritation • Systemic Toxicity • Hemo-compatibility • Material-Mediated Pyrogen • Subacute toxicity • Subchronic toxicity Material shelf-life ISO 594 • Ease of assembly ISO 80369-7 • Positive Pressure Liquid Leakage • Sub-atmospheric Pressure Air Leakage • Stress Cracking • Resistance to Separation from	Substantially Equivalent – material difference does not raise new questions of safety or effectiveness

Feature / Specification	*Predicate Device* Dual Luer Lock Cap K101385	*Subject Device* Female Luer Lock Cap	Comparison
	Axial Load • Resistance to Separation from Unscrewing • Resistance to Overriding	Axial Load • Resistance to Separation from Unscrewing • Resistance to Overriding	

PERFORMANCE DATA:

Bench testing was performed to demonstrate that the subject device is substantially equivalent to the predicate device, and that the basic design and function of the Female Luer Lock Cap complies with International Standards that specify dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for intravascular applications of medical devices and accessories.

Shelf life testing includes both simulated and real time aged product for both package integrity and product performance testing. Product and packaging underwent simulated distribution and conditioning prior to shelf life testing. Product and packaging testing are summarized in Table 5-2; testing is performed at multiple time points to support a shelf life of three years.

A product risk analysis was conducted according to ISO 14971 *Medical devices – Application of risk management to medical devices* and there were no new issues of safety and effectiveness.

Performance bench testing results meet acceptance criteria and verified the Female Luer Lock Cap meets applicable Industry Standard requirements for the design and functional performance, biocompatibility, sterilization and packaging, and demonstrates substantial equivalently to the predicate device.

Table 5-2: Performance Summary

Performance Test	Testing Standard
Luer Connector Standard	ISO 594 *Conical fittings with 6% (Luer) taper for syringes, needles, and certain other medical equipment Part 1: General & Part 2: Lock fittings* (FDA FR 6-129) • Ease of assembly

Performance Test	Testing Standard
Luer Connector Standard	ISO 80369-7 *Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications* (FDA FR 5-115) • Positive Pressure Liquid Leakage • Sub-atmospheric Pressure Air Leakage • Stress Cracking • Resistance to Separation from Axial Load • Resistance to Separation from Unscrewing • Resistance to Overriding
Biocompatibility	ISO 10993-1 *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing* (FDA FR 2-258) • Cytotoxicity • Sensitization • Intracutaneous Reactivity / Irritation • Systemic Toxicity • Hemocompatibility • Material-Mediated Pyrogen • Bacterial Endotoxins Test • Subacute Toxicity • Subchronic Toxicity
Sterilization	ANSI/AAMI/ISO 11137-1 *Sterilization of health care products. Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* (FDA FR 14-528) and ANSI/AAMI/ISO 11137-2 *Sterilization of health care products - Radiation – Part 2: Establishing the sterilization dose* (FDA FR 14-409) • VDmax15 • Sterility Assurance Level of 10^{-6}
Package Integrity	ASTM F1929-15 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration* (FDA FR 14-484) ASTM F88/F88M-15 *Standard Test Method for Seal Strength of Flexible Barrier Materials* (FDA FR 14-482)

ASSESSMENT OF CLINICAL DATA:

There were no clinical studies conducted in support of a substantial equivalence determination.

CONCLUSION:

Review of the bench performance test data as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility demonstrate that the subject device, Female Luer Lock Cap is substantially equivalent to the predicate device, the Baxter Dual Luer Lock Cap (K101385). Any differences between the subject and the predicate device do not raise any issues of safety and effectiveness.