September 15, 2021

US Infusion Inc. D/B/A Truecare Biomedix-USA
Abbey Kramarz
Director of Quality and Compliance
6356 Manor Ln Ste 101
South Miami, Florida 33143

Re: K210818
Trade/Device Name: TrueCare Biomedix Tamper Evident Cap
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: August 17, 2021
Received: August 19, 2021

Dear Abbey Kramarz:

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 CAPT Alan Stevens
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)*
K210818

Device Name
TrueCare Biomedix Tamper Evident Cap

Indications for Use *(Describe)*
Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.

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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K210818. 510K SUMMARY

TrueCare Biomedix Tamper Evident Cap

Preparation Date September 15, 2021

I. Company:

US Infusion Inc. D/B/A Truecare Biomedix-USA
6356 Manor Lane, Suite 101
South Miami, FL 33143
Telephone: (866) 593-8444

II. Contact:

Abbey Kramarz
Director of Quality and Compliance
akramarz@tcbiomedix.com

III. Proprietary Trade Name: TrueCare Biomedix Tamper Evident Cap

IV. Regulation Name: Piston Syringe
Regulation Number: 21 CFR 880.5860
Product Code: FMF
Device Class: Class ll

Predicate Device: K193192 – International Medical Industries
Prep-Lock Tamper Evident Cap

V. Product Description

The subject device is a tamper evident female luer lock cap intended for use with male luer ports on syringes. Covering luer fittings on syringes helps reduce the risk of touch contamination and medication leakage. The user group consists of those involved in pharmacy compounding as well as health care professionals.

VI. Indications for Use

Characteristic	Predicate Device International Medical Industries Prep-Lock Tamper Evident Cap K193192	Subject Device TrueCare Biomedix Tamper Evident Cap K210818
Indication for Use	Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.	Tamper Evident Caps are indicated for use as a sterile tamper evident cap for IV syringes.
Prescription Only or Over the Counter	Prescription Only	Prescription Only

Discussion of differences in Indications for Use statement:
The indication for use statement for the subject device is identical to the predicate.

VII. Summary of Technological Characteristics

Luer fittings are commonly used on syringes to provide universal compatibility. 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 subject device has been designed to be used with standard male luer connections on syringes.

The subject device's clear outer shell/housing provides tamper evidence if the cap or the contents of the container is tampered with prior to clinical administration. Once removed, the shell/housing cannot be replaced back onto the luer cap, thus making it obvious if someone has previously attempted to remove the cap and/or attempted to tamper with the contents of the syringe.

The subject TrueCare Biomedix Tamper Evident Cap is packaged in a bulk pharmacy tray with 25 caps per tray and is provided sterile via ethylene oxide sterilization.

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Technological Characteristic	**Predicate Device** **International Medical Industries Prep-Lock Tamper Evident Cap K193192**	**Subject Device** **TrueCare Biomedix Tamper Evident Cap K210818**	**Comments**
Fundamental Scientific Technology	Female luer lock cap with clear tamper evident outer shell/housing	Female luer lock cap with clear tamper evident outer shell/housing	Same
Intended Use	Cap for attachment to male luer ports on syringes	Cap for attachment to male luer ports on syringes	Same
Connection	Female luer lock	Female luer lock	Same
Tamper Evidence Feature	Clear outer shell/housing that separates from the cap upon opening	Clear outer shell/housing that separates from the cap upon opening	Same
Biocompatibility Contact / Duration	Indirect blood contact, limited duration	Indirect blood contact, limited duration	Same
Materials	Indirect patient contacting: Polypropylene with red color additive Non-patient contacting: Polystyrene	Indirect patient contacting: PP 1024 polypropylene with red color additive Non-patient contacting: Acrylonitrile Butadiene Styrene	Substantially equivalent
Sterilization	Supplied sterile via ethylene oxide (SAL of 10^{-6})	Supplied sterile via ethylene oxide (SAL of 10^{-6})	Same

Discussion of differences in technological characteristics:

Although the subject device's materials of construction are not the same as the predicate device, they are substantially equivalent based on the on biocompatibility assessment/ testing completed in support of the submission.

VIII. Brief Discussion of the Non-Clinical Tests Submitted

Performance testing

The single use, sterile TrueCare BioMedix Tamper Evident Cap described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standard:

- ISO 80369-7:2016 - Small-bore connectors for liquids and gases in healthcare applications - Part 7 Connectors for intravascular or hypodermic application

Additionally, the subject device has undergone pull-off force testing and tamper evidence functional testing per TrueCare's internal test methods to demonstrate that if the housing feature has been removed or tampered with, that it is obvious to the user.

Biocompatibility

In accordance with ISO 10993-1, the device is classified as Limited duration, externally communicating device, Blood Path Indirect (<24hours). The following testing was conducted:

- Cytoxicity
- Sensitization
- Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility

Sterility

A sterilization validation was conducted to ensure a Sterility Assurance Level (SAL) of 10^{-6} using the half-cycle overkill method in compliance with ISO 11135 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

EO and ECH residual testing was completed for the subject device per ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals and the devices met the limits of < 4mg/device and < 9mg/device, respectively.

The sterile subject devices were evaluated for the potential to produce a pyrogenic response. The Limulus Amebocyte Lysate (LAL) test was used to test for Bacterial Endotoxins as part of process validations, and the devices met the limits of < 20 EU/device. Additionally, material-mediated pyrogen testing conducted as part of the biocompatibility testing conducted in support of this submission.

The subject device is currently labeled with a 3-year shelf life based on shelf life verification testing. Packaging system characteristics and integrity testing was conducted in accordance with the following standards:

- ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISTA 2A Packaged-products weighing 150 lbs. (68kg) or less

IX. Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The TrueCare BioMedix Tamper Evident Cap is substantially equivalent to the International Medical Industries Prep-Lock Tamper Evident Cap with respect to the indications for use, target populations, treatment method, and technological characteristics.