December 11, 2017

Gemtier Medical (Shanghai) Inc.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No. 26 Quinglan Street, Panyu Dis
Guangdong, 510006
CHINA

Re: K170276
Trade/Device Name: Safety Blood Collection Device for Single Use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FPA
Dated: November 7, 2017
Received: November 9, 2017

Dear Mike Gu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known)
K170276

Device Name
Safety Blood Collection Device for Single Use

Indications for Use (Describe)
The SAFETY BLOOD COLLECTION DEVCIE FOR SINGLE USE is a single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The SAFETY BLOOD COLLECTION DEVCIE FOR SINGLE USE is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The venipuncture needle is designed to be covered with a safety mechanism, which can be activated to cover needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

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Fax: (+86) 021-57365666

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Fax: (+86) -20-8633 0253

Secondary Contact        Lenny Cao
Person:                   Sales Manager
Gemtier Medical (Shanghai) Inc.
Tel: (+86) 021-67360886
Fax: (+86) 021-57365666

Date prepared            Nov 30, 2017

2. DEVICE

Device Name:              Safety Blood Collection Device for Single Use
Common/Usual Name:       Safety Blood Collection Device for Single Use
Regulation number        21 CFR 880.5570
Regulation Name          Hypodermic single lumen needle
Regulation Class:        II
Product Code:            FMI, FPA
Classification Name      Needle, Hypodermic, Single Lumen
3. **PREDICATE DEVICES**

Predicate device: K121908, VACUETTE® SAFETY Infusion Set

These predicates have not been subject to a design-related recall.

4. **DEVICE DESCRIPTION**

The Safety Blood Collection Device for Single Use is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The Safety Blood Collection/Infusion Set is individually wrapped, sterile, non-pyrogenic and is designed for collection of blood specimens or short-term intravenous administration of fluid (up to 2 hours under direct clinical supervision). When it’s equipped with male luer adapter and/ or tube holder, it can be used for taking samples from the patients through vacuum tubes. It is also indicated for short-term intravenous fluids (up to 2 hours under direct clinical supervision) after attaching to an IV set, a transfusion set or to other compatible/appropriate device.

Three models were included in this submission, which are JT-HSQ, JT-HSQ-B, and JT-HSQ-Z.

**JT-HSQ:**

The packed JT-HSQ has been assembled with Tubing, Luer Adapter and Tube Holder. JT-HSQ can be used for blood collection directly without connecting with other part. The tubing keeps proper distance between user and patient which is convenient for user’s operation. For short-term infusion purposes (up to 2 hours), aseptically remove "Luer Adapter and Holder" from JT-HSQ prior to attaching to an IV set, a transfusion set or to other compatible/appropriate device.

**JT-HSQ-B:**

The packed JT-HSQ-B has been assembled with tubing and luer adapter, but no tube holder. Using JT-HSQ-B without tube holder’s protection is OK to collect blood but may have the risk of stick injury from blood collection needle. It’s suggested to connect JT-HSQ-B with tube holder first before blood collection. The tubing keeps proper distance between user and patient which is convenient for user’s operation. For short-term infusion purposes (up to 2 hours), aseptically remove "Luer Adapter" from JT-HSQ-B prior to attaching to an IV set, a transfusion set or to other compatible/appropriate device.

**JT-HSQ-Z:**

JT-HSQ-Z can be used for collection of blood specimens after attaching to the additional luer adapter and tube holder, it can also be used for short-term
intravenous fluids (up to 2 hours) after attaching to an IV set, a transfusion set or to other compatible/appropriate device.

5. INDICATIONS FOR USE

The SAFETY BLOOD COLLECTION DEVCE FOR SINGLE USE is a single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The SAFETY BLOOD COLLECTION DEVCE FOR SINGLE USE is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The venipuncture needle is designed to be covered with a safety mechanism, which can be activated to cover needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 6.1 Comparison with Predicate Device

<table>
<thead>
<tr>
<th>Specification</th>
<th>Predicate Device</th>
<th>Proposed Device</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device name</td>
<td>VACUETTE® SAFETY Infusion Set</td>
<td>SAFETY BLOOD COLLECTION DEVCE FOR SINGLE USE</td>
<td></td>
</tr>
<tr>
<td>K number</td>
<td>K121908</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Product code and classification name</td>
<td>FMI, Needle, Hypodermic, Single Lumen</td>
<td>FMI, Needle, Hypodermic, Single Lumen</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Greiner Bio-One GmbH</td>
<td>Gemtier Medical (Shanghai) Inc.</td>
<td></td>
</tr>
<tr>
<td>Indications for use</td>
<td>The VACUETTE® SAFETY Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing* with a luer connector. The VACUETTE® SAFETY Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.</td>
<td>The SAFETY BLOOD COLLECTION DEVCE FOR SINGLE USE is a single-use, sterile, winged blood collection needle bonded or not to a flexible tubing with or without a luer adapter and/or tube holder. The SAFETY BLOOD COLLECTION DEVCE FOR SINGLE USE is used for blood collection and/or the short-term infusion of intravenous fluids. The venipuncture needle is designed to be covered with a safety mechanism, which can be activated to cover needle immediately following venipuncture to aid in the protection against accidental needlestick injury.</td>
<td>Identical</td>
</tr>
</tbody>
</table>
## Specification

<table>
<thead>
<tr>
<th>Specification</th>
<th>Predicate Device</th>
<th>Proposed Device</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicated for infusion</td>
<td></td>
<td>Yes</td>
<td>Identical</td>
</tr>
<tr>
<td>Single use</td>
<td></td>
<td>Yes</td>
<td>Identical</td>
</tr>
<tr>
<td>Mechanism of safety blood collection</td>
<td></td>
<td>Latch mechanism for sharps injury protection</td>
<td>Identical</td>
</tr>
</tbody>
</table>

## Materials

<table>
<thead>
<tr>
<th>Component</th>
<th>Predicate Device</th>
<th>Proposed Device</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venipuncture Needle</td>
<td></td>
<td>Stainless steel</td>
<td>Identical</td>
</tr>
<tr>
<td>Blood Collection Needle</td>
<td></td>
<td>Stainless steel</td>
<td>Identical</td>
</tr>
<tr>
<td>Tubing</td>
<td>PVC</td>
<td>PVC</td>
<td>Identical</td>
</tr>
<tr>
<td>Wing</td>
<td>PVC</td>
<td>PVC</td>
<td>Identical</td>
</tr>
<tr>
<td>Sleeve</td>
<td>PE</td>
<td>PE</td>
<td>Identical</td>
</tr>
<tr>
<td>Retractable Cartridge</td>
<td>PC</td>
<td>PC</td>
<td>Identical</td>
</tr>
<tr>
<td>Female luer connector</td>
<td>ABS</td>
<td>ABS</td>
<td>Identical</td>
</tr>
<tr>
<td>Male luer protector</td>
<td>PP</td>
<td>PP</td>
<td>Identical</td>
</tr>
<tr>
<td>Male Luer adapter</td>
<td>N/A</td>
<td>ABS</td>
<td>Identical</td>
</tr>
<tr>
<td>Tube holder</td>
<td>N/A</td>
<td>PP</td>
<td>Identical</td>
</tr>
<tr>
<td>Blood collection needle protector</td>
<td>N/A</td>
<td>PP</td>
<td></td>
</tr>
<tr>
<td>Rubber cover</td>
<td>N/A</td>
<td>Synthetic Rubber</td>
<td></td>
</tr>
</tbody>
</table>

## Components

<table>
<thead>
<tr>
<th>Component</th>
<th>Predicate Device</th>
<th>Proposed Device</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubing, Wing, Female luer connector</td>
<td></td>
<td>Yes</td>
<td>Identical</td>
</tr>
<tr>
<td>Plastic Sleeve, Venipuncture Needle Stand</td>
<td></td>
<td>Yes</td>
<td>Identical</td>
</tr>
<tr>
<td>Specification</td>
<td>Predicate Device</td>
<td>Proposed Device</td>
<td>Discussion of Differences</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Mechanism of safety blood collection</td>
<td>Yes, slide the safety mechanism to activate</td>
<td>Yes, Press both sides of the safety mechanism to release the lock first and slide the safety mechanism to activate</td>
<td>Similar This difference does not raise difference questions of safety and effectiveness.</td>
</tr>
<tr>
<td>Male Luer adapter, Tube holder,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Collection Needle, Blood collection needle protector structure</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**Performance Specifications**

<table>
<thead>
<tr>
<th>Specification</th>
<th>Predicate</th>
<th>Proposed</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle Gauge Size(s)</td>
<td>21G, 23G, 25G</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td>Needle Wall</td>
<td>Thin Wall</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td>Needle Length Size(s)</td>
<td>19mm</td>
<td>20mm</td>
<td>Similar This difference does not raise difference questions of safety and effectiveness.</td>
</tr>
<tr>
<td>Needle Point</td>
<td>3 bevel</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td>Tubing Length</td>
<td>From 10cm to 30cm</td>
<td>From 10cm to 35cm</td>
<td>Similar This difference does not raise difference questions of safety and effectiveness.</td>
</tr>
<tr>
<td>Sterile</td>
<td>Yes</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>EO Sterilization</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td>Non-pyrogen</td>
<td>Yes</td>
<td>Identical</td>
<td></td>
</tr>
<tr>
<td>Shelf Life</td>
<td>5 years</td>
<td>3 years</td>
<td>Similar This difference does not raise difference questions of safety and effectiveness.</td>
</tr>
</tbody>
</table>
## Speciation

<table>
<thead>
<tr>
<th>Specification</th>
<th>Predicate Device</th>
<th>Proposed Device</th>
<th>Discussion of Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocompatibility</td>
<td>Cytotoxicity, Skin Sensitization, Irritation, Acute Systemic Toxicity, Haemolysis, Pyrogenicity, Bacterial Endotoxins</td>
<td></td>
<td>Identical</td>
</tr>
</tbody>
</table>

Compared with the predicate device, VACUETTE® SAFETY Infusion Set (K121908), the proposed device is identical in indications for use, mechanism of action, materials, needle wall and point, sterilization method, and biocompatibility.

The proposed device has the same components, except for adding male luer adapter, tube holder, blood collection needle protector and rubber cover.

The proposed device has the same performance specifications, except for additional needle gauge sizes, similar needle length, similar tubing length and a shorter shelf life. Through performance bench testing the proposed device and the predicate device demonstrated to be substantial equivalence.

### 7. NON-CLINICAL DATA

The following non-clinical data were provided in support of the substantial equivalence determination.

#### Biocompatibility testing

The biocompatibility evaluation for the Safety Blood Collection Device for Single Use was conducted in accordance with the International Standard ISO 10993-1:2009/(R)2013, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Irritation
- Acute Systemic Toxicity
- Haemolysis
- Pyrogenicity
- Bacterial Endotoxins

The device is classified as direct blood path. The duration of contact is less than 24 hours. The test results of cytotoxicity, skin sensitization, irritation, acute systemic toxicity, haemolysis, pyrogenicity and bacterial endotoxins complied with ISO 10993 standards, including ISO 10993-4:2002+Amd 1:2006, Biological Evaluation of medical

Performance testing

Performance tests were conducted on the Safety Blood Collection Device for Single Use, according to the following standards and guidance,

Tests conducted: Particulate contamination, leakage, tensile strength, tubing appearance, flow rate, protective caps, chemical requirements, reducing (oxidizable) matter, metal ions, titration acidity or alkalinity, residue on evaporation, uv absorption of extract solution.

(2) ISO 80369-7:2016. Small-bore connectors for liquids and gases in healthcare applications -- Part 7: Connectors for intravascular or hypodermic applications.
Tests conducted: Dimensional requirement, gauging test, fluid leakage, sub-atmospheric pressure air leakage, stress cracking, resistance to separation from axial load, resistance to separation from unscrewing, resistance to overriding.

Tests conducted: Surface finish and visual appearance, cleanliness, limits for acidity and alkalinity, size designation, dimensions, stiffness, resistance to breakage, resistance to corrosion.

(4) ISO 7864:2016. Sterile hypodermic needles for single use -- Requirements and test method
Tests conducted: Cleanliness, limits for acidity and alkalinity, limits for extractable metals, size designation, colour coding, needle hub requirement, needle cap requirement, needle tube requirement, needle point requirement, bond between hub and needle tube requirement, patency of lumen, sharps injury protection.

Tests conducted: Simulated clinical performance validation of sharp protection features.

The requirements of the above standards and guidance were met in all test devices.

Comparative performance testing was conducted between the proposed device and the predicate device, VACUETTE® SAFETY Infusion Set, to evaluate the physical and chemical performance specifications. Both the proposed device and predicate device met the requirements of ISO 8536-4: 2010, ISO 80369-7: 2016, ISO 9626: 2016, ISO 7864: 2016, ISO 23908: 2011 and FDA guidance Simulated Clinical Use Testing of the FDA Guidance on Medical Devices with Sharps Injury Prevention Features, and the testing results demonstrated substantial equivalences between the proposed device with the predicate device.

8. CONCLUSION

The non-clinical data demonstrate that the Safety Blood Collection Device for Single Use performed as intended in the specified use conditions. Through performance bench testing the subject device has demonstrated that they are substantially equivalent to the predicate device.