July 30, 2019

NSP Tech Pte Ltd
HC Tan
10 Admiralty Street,
Northlink Building, #02-06
757695
Singapore

Re: K181754
Trade/Device Name: Blood Collection Accessory (BUCA)
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: April 16, 2019
Received: June 28, 2019

Dear HC Tan:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181754

Device Name
Blood Collection Accessory (BUCA)

Indications for Use *(Describe)*
The Blood Collection Accessory (BUCA) is a single use, sterile and non invasive device used for connecting to venous access device for the collection of blood specimens.

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 (K181754)

1. SUBMITTER:

Applicant Name:

NSP Tech Pte Ltd
10 Admiralty Street,
Northlink Building, #02-06
Singapore 757695

Contact Person:

Name: HC Tan

Phone: (65)98180450

Fax: (65)67476533
Email: hockchoon.tan@nsptech.com.sg

Establishment registration number : 3008337059

Date prepared : July 29, 2019

2. DEVICE

Trade Name : Blood Collection Accessory (BUCA)

Common Name : Blood Specimen Collection Device

Regulatory Class : Class II

Regulation Number: 21 CFR 862.1675

Regulation Name: Blood Specimen Collection Device

Product Code : JKA

Panel : Clinical Chemistry

3. PREDICATE DEVICE

Vacutainer® Brand Multiple Sample Luer Adapter

510(k) Number: K991088

Regulatory Class: Class II

Regulation Number: 21 CR 862.1675

Product Code: JKA

4. DEVICE DESCRIPTION:

The Blood Collection Accessory (BUCA) is a single use device comprising of a holder made from polypropylene plastic with a male luer feature. A stainless-steel needle covered with a rubber sleeve is attached to the inside of the holder.

The Blood Collection Accessory (BUCA) has a Holder that encases the Needle preventing any needle stick issue with user. The Holder of the Blood Collection Accessory (BUCA) also house the sample collection tube and protects the user or healthcare personnel from direct

contact with blood specimen. The Adapter connected to the blood collection device for the blood transfer. The sample collection tube is inserted from the far end of the holder where the opening is located. This transfer is conducted until the required amount of blood is completed. The sample collection tube is then evacuated from the Blood Collection Accessory (BUCA) by pulling it away from the latter.

5. INDICATION FOR USE STATEMENT

The Blood Collection Accessory (BUCA) is a single use, sterile and non invasive device used for connecting to venous access device for the collection of blood specimens.

6. SUBSTANTIAL EQUIVALENCE COMPARISON

TABLE OF COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

	NSP Tech Pte Ltd Blood Collection Accessory (BUCA)	**Vacutainer® Brand Multiple Sample Luer Adapter**	**Discussion/Comment**
510 (k) Number	K181754	K991088	
Classification	Class II	Class II	same
Product Code	JKA	JKA	same
Indication For Use	The Blood Collection Accessory (BUCA) is a single use, sterile and non invasive device used for connecting to venous access device for the collection of blood specimens.	The Vacutainer Brand Luer Adapter is a sterile, non-invasive device used to connect venous access devices such as needles, blood collection sets, and infusion sets to blood collection tubes. They are also used in connection with non-needle devices for collection of blood from catheters. The Vacutainer Brand Luer Adapter is sold by itself and as a component of other Vacutainer Brand devices.	Similar- The difference is in the name of the device, this does not raise any questions of safety or effectiveness. The predicate specifies the devices that it connects with and the subject device does not.
Manufacturer	NSP Tech Pte Ltd	Becton Dickinson	

Product Configuration	Holder – Polypropylene Adapter - Acrylonitrile butadiene styrene Sleeve – Not made with natural rubber latex Needle – Stainless Steel	Holder – Polypropylene Adapter - Polycarbonate Sleeve – Not made with natural rubber latex Needle – Stainless Steel	The only major difference between the subject device and the predicate device is in the material used for the part, Adapter. The subject device, Blood Collection Accessory (BUCA) uses the polymer, Acrylonitrile butadiene styrene (ABS) for the Adapter part while the predicate device uses Polycarbonate (PC) polymer. Biocompatibility Testing and Performance Testing was conducted to demonstrate SE.
Sterilization	Ethylene Oxide (EtO) Gas sterilization	Ethylene Oxide (EtO) Gas sterilization	same
Sterility	Meet the Sterility Assurance Level of 10-6 as per the requirement of ISO 11135:2014	Not known	Non-Clinical Performance Testing was conducted to demonstrate SE.
Packaging	Sealed Blister Packaging	Sealed Blister Packaging	Non-Clinical Performance Testing was conducted to demonstrate SE.
Use	Single-Use only	Single-Use only	same
Bio compatibility	ISO 10993 series	ISO 10993 series	same
Shelf Life	1 year	3 years	Non-Clinical Performance Testing was conducted to demonstrate SE.

7. TECHNOLOGICAL CHARACTERISTICS COMPARISON

The Blood Collection Accessory (BUCA) device has similarities with the predicate device in areas such as Intended Use Product Configuration, and performance.. The only difference between the subject device and the predicate device is in the use of material for the part, Adapter. The Blood Collection Accessory (BUCA) uses the polymer material, Acrylonitrile butadiene styrene (ABS) while the

predicate device uses the polymer material, Polycarbonate (PC). Biocompatibility tests and performance tests based on international standards demonstrated the device performs as intended. The indications for use of the predicate device specifies the blood collection devices it connects to. The Subject device does not specify the blood collection devices, this does not raise different questions of safety or effectiveness.

8. Performance Data/Non-Clinical Testing:

The Blood Collection Accessory (BUCA) was tested for validation and verification of functions based on risk analysis and the results passed predetermined acceptance criteria.

Biocompatibility

Biocompatibility was evaluated per the FDA Guidance titled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff issued in June 2016 with the following endpoints:

Cytotoxicity

Sensitization

Irritation

Acute Systemic Toxicity

Pyrogenicity

Hemocompatibility (Coagulation, Platelets and Hemolysis)

Performance Data

Performance testing was carried out on the Blood Collection Accessory (BUCA) using applicable international standards as reference and predicate device as benchmark for comparison.

- Luer Lok Adapter

  For international standard related test, the Luer Lok adapter is tested with reference to the ISO 80369-7:2016 and ISO 80369-20:2015.

- Performance Testing

  As for the benchmarking tests related to the predicate device, blood collection performances such as the flow rate and quality of holder, holding strength of sleeve to adapter and needle to adapter are assessed and compared against that of the predicate device.. The test methods employed are as summarized below:

  - Flow Rate Test - The time taken to fill up a 3.0 ml blood collection tube with liquid of viscosity similar to blood is recorded.

- Leakage Test- With the device held in place by a fixture, the maximum numbers of round of insertion and evacuation of blood collection tube the device can withstand before leakage start occurring at the device is recorded.
- Evacuation Force Test - The device is held in place by a fixture and a force taken to insert or evacuate a blood collection tube into the holder of the device is recorded.
- Holding Strength of Needle to Adapter Test - Using fixture to hold the adapter in place, the needle is pull in a direction away from the adapter. The force taken to dislodge the needle from the adapter is recorded.
- Holding Strength of Sleeve to Adapter Test - With the adapter held in place by a fixture, the sleeve is pull in a direction away from the adapter and the force taken to dislodge the sleeve from the adapter is recorded.
- Deformation Test The device is held in place by a fixture and a 5 kg force is applied on the device for a period of 5 minutes. The permanent change in outer diameter of the holder of the device before and after compression by the applied force is measured and recorded. This test assesses the quality of the holder.

Sterilization

Sterilization is done in accordance to ISO 11135-1:2014.

The Sterility Assurance Level (SAL) is 10^{-6}.

9. SUBSTANTIAL EQUIVALENCE CONCLUSION

The result of non-clinical testing demonstrates that the Blood Collection Accessory (BUCA) is substantially to the predicate device, Vacutainer® Brand Multiple Sample Luer Adapter and has been demonstrated to meet its predetermined specifications.