April 21, 2020

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

Re: K193074
Trade/Device Name: Bevel Up Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: March 2, 2020
Received: March 4, 2020

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 Tina Kiang Ph.D.
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)*
K193074

Device Name

BEVEL UP HOLDER

Indications for Use *(Describe)*

The Bevel Up Holder is used for the collection of blood into blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles and tubes. The device is to be used by trained healthcare professional only.

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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510(k) Summary (K193074)
Bevel Up Holder (BUH)

I. SUBMITTER:

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

Phone: (65) 67478177

Contact Person:
Name: HC Tan
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Fax: (65) 67476533
Email: hockchoon.tan@nsptech.com.sg

Date Prepared:
20th February 2020

II. DEVICE

Name	:	Bevel Up Holder
Trade Name	:	BUH
Common Name	:	Blood Collection Tube Holder
Classification Name	:	Blood Specimen Collection Device
Regulatory code	:	21 CFR 862.1675
Regulatory Class	:	Class II
Product Code	:	JKA

III. PREDICATE DEVICE:

Trade Name	:	VACUETTE Blood Culture Holder
510(K) Number	:	K122687
Common Name	:	Blood Collection Tube Holder

Classification Name	:	Blood Specimen Collection Device
Regulatory code	:	21 CFR 862.1675
Regulatory Class	:	Class II
Product Code	:	JKA

IV. DEVICE DESCRIPTION

The Bevel Up Holder device is a single use and non-invasive device to be used in venipuncture procedures for the collection of blood specimens. It is to be used as a Tube Holder with blood collection tubes such as the Becton Dickinson Vacutainer® blood collection tube. The Bevel Up Holder device is also used with blood collection needles and blood collection sets such as the Becton Dickinson Eclipse Needle set, Becton Dickinson Vacutainer Multi Sample and Becton Dickinson Safety Lok Blood Collection Set for the collection of blood specimen into the blood collection tubes. The Bevel Up Holder is to be used by trained healthcare professional only and is intended for prescription use.

The Bevel Up Holder has a clear plastic holder body with an opening on one end for the insertion of blood collection tube and an interface device connecting feature on the other end for venous access device for connecting to blood collection needle and blood collection set.

The connecting end of the venous access device of the Bevel Up Holder (BUH) device allows the adjusting of the position of the venous access device with rotating it.

V. INDICATIONS FOR USE STATEMENT

The Bevel Up Holder is used for the collection of blood into blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles and tubes. The device is to be used by trained healthcare professional only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Bevel Up Holder (BUH) and the predicate device.

The following comparison chart shows that the subject device and the predicate device are substantially equivalent:

TABLE OF COMPARISON BETWEEN SUBJECT DEVICE AND PREDICATE DEVICE

510(k) Summary (K193074)
Bevel Up Holder (BUH)

Device Name	NSP Tech Pte Ltd Bevel Up Holder (BUH)	Greiner Bio One VACUETTE® Blood Culture Holder
510(k) Number	K193074	K122687
Classification	Class II	Class II
Product Code	JKA	JKA

Device Name	NSP Tech Pte Ltd Bevel Up Holder (BUH)	Greiner Bio One VACUETTE® Blood Culture Holder	Comparison
Indications For Use	The Bevel Up Holder is used for the collection of blood into blood collection tubes in routine venipuncture procedures. It is used with blood collection sets, needles and tubes. The device is to be used by trained healthcare professional only.	The Blood Culture Holder is used to fill blood into blood culture bottles and tubes in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with these instructions.	Both the Bevel Up Holder and the predicate device are used for collection of blood into collection tubes carried out in routine venipuncture procedures by trained healthcare professional. Hence, they are similar in the Indication For Use.
Manufacturer	NSP Tech Pte Ltd	Greiner Bio One	N/A
Product Configuration	Clear plastic Holder	Clear plastic Holder	Same
Material	Polypropylene	Polypropylene	Same
Sterility	Not sterilized	Not sterilized	Same

Packaging	Bulk pack in poly bag	Bulk pack in poly bag.	Same
Use	Single-Use Only	Single-Use Only	Same
Bio Compatibility	~~Leveraged from Blood Transfer Accessory (K181743)~~10993 series	ISO 10993 series	~~Same~~Same
Shelf Life	3 years	3 years	Same

Similarities:

The Bevel Up Holder device has similarities with the predicate device in areas such as Indications For Use, Product configuration, Material used, Principle of operations of safety feature and technological characteristics. The safety and effectiveness of the two devices are similar.

Differences:

The Bevel Up Holder device differs from the predicate device in the design where the latter has a bluish appearance for the color of the device.

VII. PERFORMANCE DATA

Simulated blood collection was performed on the Bevel Up Holder using the respective interface devices each time which is the

- Becton Dickinson Eclipse Needle Set
- Becton Dickinson Vacutainer Multi Sample
- Becton Dickinson Safety Lok Blood Collection Set

For each of the above interface device, the test involves using a new Bevel Up Holder connected to a new set of interface device each time and the blood collection process carried out. This is done with 20 sets of the subject device and interface device. The results were evaluated for proper fit, leakage and function of the devices. All Bevel Up Holders met the acceptance criteria for fit, leakage and function when used for blood collection. The device meets the functional and performance requirements, underwent testing in accordance with the following recognized consensus standards:

- ASTM D4169-16: Standard practice for performance testing of shipping containers and systems.
- ISO 14971;2007: Medical Devices-Application of Risk management of medical devices
- ASTM F88/F883-15: Standard test method for seal strength of flexible barrier materials

In addition, the following performance testing was carried out on the Bevel Up Holder.

- **Deformation Test**

  The device was tested by holding it in place with a fixture and a 5 kg force is applied on the device for a period of 5 minutes. Any permanent change in outer diameter of the device before and after compression by the applied force is measured and recorded. This test assesses the quality of the device. Result of the test shows no permanent change in the outer diameter of the Bevel Up Holder (BUH).

- **Insertion and Evacuation Force Test**

  The device is held in place by a fixture and the force taken to insert or evacuate a blood collection tube into the device is recorded and result shows the device meeting the defined acceptance criteria in the insertion and evacuation of the blood collection tube into the Bevel Up Holder (BUH) for blood collection operation.

- **Connectivity Test**

  The device was tested for connectivity by connecting them to the interface devices such as Becton Dickinson Eclipse Needle Set, Becton Dickinson Vacutainer Multi Sample and Becton Dickinson Safety Lok Blood Collection Set for the test with each of the respective devices. The blood collection operation is then simulated and result shows no leakage with good fit and function for the connectivity of the Bevel Up Holder (BUH) to the interface devices.

- **Test: Shelf Life**

  An Accelerated Aging Test is done with reference to ASTM F1980-2007 is conducted for the device to simulate the defined years of shelf life. Result shows that the Bevel Up Holder (BUH) meeting the defined shelf life with device still functioning well.

- **Bio Compatibility**

  The Bevel Up Holder device in its finished form is identical to Blood Transfer Accessory (K181743) in formulation (material), processing, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).Leveraging on the bio compatibility result of this similar identical device, the Bevel Up Holder (BUH) is deemed to have met the biocompatibility requirements for Cytotoxicity, Sensitization and Irritation Reactivity.

- **Sterilization**

  The device is not required to be sterilized.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION

The result of the non-clinical testing demonstrates that the Bevel Up Holder (BUH) is substantially equivalent to the predicate device, VACUETTE® Blood Culture Holder.

Hence, we conclude that based on the information above, the Bevel Up Holder (BUH) is substantially equivalent to the predicate device, VACUETTE® Blood Culture Holder.