December 14, 2021

Vacutest Kima Srl
Elisa Buggio
Regulatory Assistant
Via dell'Industria 12
Arzegrande, Padova 35020
Italy

Re: K200932
Trade/Device Name: Blood Collection Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 10, 2021
Received: November 15, 2021

Dear Elisa Buggio:

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,

Gang Peng For
Payal Patel
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)*
K200932

Device Name
Blood Collection Needles

Indications for Use *(Describe)*
The Blood Collection Needles are sterile, single use medical devices specifically intended to be used by trained healthcare professionals for the collection of blood samples into evacuated blood collection tubes.
The Safety Blood Collection Needles are sterile, single use medical devices specifically intended to be used by trained healthcare professionals for the collection of blood samples into evacuated blood collection tubes; they are designed with a safety mechanism, which can be activated to cover the needle immediately after puncture to provide protection from accidental needle sticks.

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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K200932 510(k) Summary

Prepared Date:	December 8, 2021
Applicant:	
Company Name:	Vacutest Kima s.r.l
Company Address:	Via dell'Industria 12 35020 Arzegrande (Padova) - Italy
Company Phone:	+39 049 9719511
Company Fax:	+39 049 9719542
Company e-mail	info@vacutestkima.it
Official Contact for Correspondence:	Buggio Elisa
Phone:	+39 049 9719511
E-mail:	regulatory@kima.it

DEVICE IDENTIFICATION

Trade name:	Blood Collection Needles
Generic/ Common Name:	Hypodermic needles
Classification:	21 CFR §880.5570 Class II
Classification name:	Hypodermic single lumen needle
Product Code:	FMI
Panel:	General Hospital

PREDICATE DEVICE:

K982541	BD Vacutainer® Eclipse™ Blood Collection Needle, BECTON DICKINSON VACUTAINER SYSTEMS

DEVICE DESCRIPTION

The Vacutest Kima blood collection needles are sterile and disposable single use devices intended for the daily blood collection routine.
They are intended for single or multiple blood collection from one single patient, with vacuum blood collection tubes. The needles must be applied on a holder; a separate use is not possible.
The Safety Needle models feature a mechanism covering the needle after use; in these models a holder with pre-assembled safety cover is part of the device. The safety mechanism applied to the holder requires no change of the operative manners for blood collection.

Gauge	Length
18g, 20g, 21g, 22g	1 ½ "& 1"
20g, 21g, 22g (Needle safety feature)	1 ½ "& 1"

INDICATIONS FOR USE

The Blood Collection Needles are sterile, single use medical devices specifically intended to be used by trained healthcare professionals for the collection of blood samples into evacuated blood collection tubes.
The Safety Blood Collection Needles are sterile, single use medical devices specifically intended to be used by trained healthcare professionals for the collection of blood samples into evacuated blood collection tubes; they are designed with a safety mechanism, which can be activated to cover the needle immediately after puncture to provide protection from accidental needle sticks.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Attribute / Characteristics	Blood Collection Needles (Submitted Product)	BD Vacutainer® Eclipse™ Blood Collection Needle, (Legally Marketed Predicate Device)	Comparison
'K" numbers	**K200932**	**K982541**	
CFR Section	880.5570	880.5570	same
Pro-code	FMI	FMI	same
Classification name	Hypodermic single lumen needle	Hypodermic single lumen needle	same
Intended / Indications for Use	The Blood Collection Needles are sterile, single use medical devices specifically intended to be used by trained healthcare professionals for the collection of blood samples into evacuated blood collection tubes. The Safety Blood Collection Needles are sterile, single use medical devices specifically intended to be used by trained healthcare professionals for the collection of blood samples into evacuated blood collection tubes; they are designed with a safety mechanism, which can be activated to cover the needle immediately after puncture to provide protection from accidental needle sticks.	The BD Vacutainer® Eclipse™ Blood Collection Needle is a sterile, multiple sample, single-use device for blood collection. The needle is designed with an attached safety shield, which can be activated to cover the needle immediately after venipuncture to provide protection from accidental needle sticks.	Comment #1 Different: both the subject and the predicatedevice are indicated for use in clinical environments forblood collection; the subject device is also offered withoutsafety mechanism, but this does not impact the device's diagnostic/ therapeutic use or raise new questions of safety or effectiveness as compared to the predicate
Cannula material	AISI 304 Stainless Steel	AISI 304 Stainless Steel	same

Attribute / Characteristics	Blood Collection Needles (Submitted Product)	BD Vacutainer® Eclipse™ Blood Collection Needle, (Legally Marketed Predicate Device)	Comparison
Hub material	Polypropylene (PP)	Polystyrene (PS)	Different: both polymers; PP iscommonly used to Manufacture plastic laboratory supplies
Hub color	color coded ISO 6009	color coded ISO 6009	same
Rubber sleeve	synthetic Isoprene	synthetic Isoprene	same
Cover	rigid cover, polypropylene	rigid cover, polyethylene	same
Adhesive	epoxy type adhesive	epoxy type adhesive	same
Lubricant	medical grade silicone oils	medical grade silicone oils	same
Needle diameter (gauge)	18G, 20G, 21 G, 22G	21 G, 22G	Comment #2 Different: The submitted device is offered in a wider range of needle options in comparisonto the predicate device; this does not affect the operation of the device, as proved by thenon-clinical tests performed on the subject device.
Needle length	1 inch, 1 ½ inch	1 ¼ inch	Comment #2 Different: The differences in the needle length between the subject and the primary predicate device do not impact the subject device performances; there are no potential issues of safety and effectiveness forthese differences in the lengthof the needle, as proved by the non-clinical testsperformed on the subject device
Tip configuration	double tipped: the longest portion of the needle is used to puncture the patient's vein, the shortest part fits inside the tube holder	double tipped: the longest portion of the needle is used to puncture the patient's vein, the shortest part fits inside the tube holder	same
Shelf life	3 years	5 years	Different: The shorter shelf life of the subject device poses no newissues of safety and effectiveness in comparison to the longer shelf life of the predicate device

Attribute / Characteristics	Blood Collection Needles (Submitted Product)	BD Vacutainer® Eclipse™ Blood Collection Needle, (Legally Marketed Predicate Device)	Comparison
Primary Packaging	individually packed with a plastic cover composed by 2 parts sealed with a label or packed in sealed individual blisters	individually sealed sterile pouch	Different: Both the packaging systems used for the subject devices are validated and the SAL is 10^{-6} substantially equivalent
Secondary Packaging	cardboard box	cardboard box	same
Sterilization	Ethylene Oxide (EO) SAL 10^{-6}	Gamma irradiation SAL 10^{-6}	Comment #3 Different: A different sterilizationmethod is applied on the subject device in comparison with the predicate device, butthe assurance sterility level is the same. Thus, no issues of safety arise.
Biocompatibility	ISO 10993-1	ISO 10993-1	same
Functional testing	Testing in compliance with ISO 7864:2016 ISO 9626:2016 ISO 23908:2011	ISO 7864:1993 ISO 9626:1991	Different: the subject device contains testing for the safety feature

Predicate Device Comparison Chart - sharps injury prevention feature

Sharps injury prevention feature	Blood Collection Needles (Submitted Product)	BD Vacutainer® Eclipse™ Blood Collection Needle (Legally Marketed Predicate Device)	Comparison
Material	Plastic (PP)	Plastic (PP)	same
Pigments	Transparent Light blue	Transparent pink	Different: Both mechanisms are made with transparent plastic that allows the operator to see thecorrect closure of the safety device
Bonding agents	None	None	same
Technical description	The safety shield is connected to the holder. The safety needle cover is positioned so as not to interfere with blood collection; it can be rotated to find a suitable position during the blood collection. Activation can be done by the user with a single-handed technique. Once activated, the safety device completely encloses the needle and cannot be disengaged. Length: 53.5	The safety shield is connected to the needle, in a fixed position thus it can't be rotated. Activation can be done by the user with a single-handed technique. Once activated, the shield completely enclose the needle, mechanism cannot be disengaged. Length 47.70 Distance from the holder: 11 mm	Different: In the predicate device the safety shield is connected to the needle, in a fixed position, while in the subject device it is connected to the holder and it can rotate. This difference in the design of the subject device facilitates the blood collection and does not affect the safety and effectiveness of the subject device, as proved by the benching tests performed.
Principle of operation	Rotate the light blue safety needle cover towards the bottom of holder. Remove the transparent needle cover. Perform blood collection according to safety procedures. Immediately after the blood collection, activate the safety device with a thumb. The safety device is close to holder so that the single hand technique activation could be done simply sliding the thumb along the wall of the holder. Closing operation ends after hearing a click and with the visual check of locking of needle.	Gently position pink safety shield straight back toward the holder. Twist and pull colored needle cap straight off. Holding the barrel of the holder, perform venipuncture per your facility's procedure. Immediately after removing needle from vein, position thumb squarely on pink safety shield thumb pad and push pink safety shield forward to cover needle. An audible click may be heard. Lock shield into place and inspect. Do not attempt to engage safety shield by pressing against a hard surface.	Different: Both devices can be activated with a single hand technique and cannot be disengaged. Both devices are in a position so as not to interfere with blood collection. In the submitted product the safety device can be rotated to find a suitable position to perform the venipuncture.
Activation Method	Activate the safety device with a thumb simply sliding the thumb along the wall of the holder. Closing operation ends after hearing a click and with the visual check of locking of needle.	Position thumb squarely on pink safety shield thumb pad and push pink safety shield forward to cover needle. An audible click may be heard. Lock shield into place and inspect.	Different: The safety mechanism is activated in both the devices by pushing it with the thumb. The activation method of the submitted device allows the operator to close the safety device keeping the holder in the same position during all blood collection procedure.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

Comment #1

The Blood Collection Needles are same or similar in intended use, materials and design to the predicate device (K982541). Both the subject and the predicate device are indicated for use in clinical environments for blood collection. Both the devices have the same principle of operation, same overall design, including use of a holder; the same method of use and very limited duration of contact (≤ 3 min.) with patient's blood; the same cannula material, similar geometry and gauge.
Both the subject and the predicate device are provided with or without a preassembled holder.
The subject device is also offered without safety mechanism, but this does not impact the device's diagnostic/therapeutic use or raise new questions of safety or effectiveness as compared to the predicate. As for the safety mechanism, the subject device is substantially equivalent to the predicate device in materials, design and principle of operation of the sharps injury prevention feature; the slight differences do not affect the safety and effectiveness of the safety shield of the subject device, as proved by the benching tests performed.

Comment #2

The subject device is available in sizes 18g-22g inch x 1 ½ & 1 inch lengths, the predicate device is available in sizes 21g-22g x 1 ¼ inch. Venous flow through the inner diameter of the cannula into attached blood collection tubes is the technological principle for both the subject and predicate device. The subject and predicate device are based on the same or similar technological elements and are made with the same materials, largely used for the same type of medical devices already on the market.
The minor differences in gauge and length of the devices do not impact the safety and effectiveness of the subject device. The performance data (design verification testing) demonstrate that the subject device is as safe and effective as the cited predicates. Thus, the Blood Collection Needles are substantially equivalent to the proposed predicate device.

Comment #3
There are minor differences in sterilization method and shelf life. Sterilization validation, shelf-life and package integrity testing demonstrate that the subject device maintains its sterility and performance through its expiration. These differences do not raise any new types of safety or effectiveness questions.

DISCUSSION OF NON-CLINICAL TESTS

<u>Biocompatibility</u>
In accordance with ISO 10993-1, the Blood Collection Needle is classified as Externally Communicating Device, Blood Path Direct, Limited Contact (<24 hours). The following testing was conducted:

- ISO 10993-5:2009, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006, Biological evaluation of medical devices — Part 11: Tests for systemic
- USP 41 <151>, Material Mediated pyrogenicity
- ASTM F756-08, "Standard Practice for Assessment of Haemolytic Properties of Materials
- ISO 10993-4:2002/Amd 1:2006: "Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- USP<788>, Particulate matter in injections

Sterilization Validation

The sterile Blood Collection Needle described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 11135:2014, Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices,
- ISO 11138-1: 2017, Sterilization of health care products -- Biological indicators – Part 1: General requirements.
- ISO 10993-7 :2008, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.
- ISO 11607-1:2009, Packaging for terminally sterilized medical devices-Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2006, Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly processes
- ISO 11737-1:2018, Sterilization of health care products-Microbiological methods- Part1: Determination of a population of microorganisms on products.
- ISO 11737-2:2009, Sterilization of medical devices-Microbiological methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

- LAL test was performed according to:
  - USP 39th ed. 2016: <85> Bacterial Endotoxins Test
  - USP 39th ed. 2016: <161> Transfusion and infusion assemblies and similar medical devices.
  - European Pharmacopoeia current edition: 2.6.14 Bacterial Endotoxins.

Performance Testing

The sterile, Blood Collection Needles described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7864:2016, “Requirements and test methods Sterile hypodermic needles for single use. Requirements and test methods”,
- ISO 9626:2016, “Stainless steel needle tubing for the manufacture of medical devices. Requirements and test methods”
- ISO 23908:2011, “Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

CONCLUSION:

The differences between the predicate device and the subject device do not raise any new or different questions of safety or effectiveness. The Blood Collection Needle is substantially equivalent to the BD Vacutainer Blood Collection Needle.