Retractable Technologies, Inc.
Becky Piroga
Regulatory Affairs Manager
511 Lobo Lane
Little Elm, Texas 75068

Re: K202325
Trade/Device Name: EasyPoint Blood Collection Plus
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA, FMI
Dated: March 1, 2021
Received: March 9, 2021

Dear Becky Piroga:

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,

James M. Simpson Jr -S7

for Payal Patel
Acting 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)*

K202325

Device Name
EasyPoint® Blood Collection Plus

Indications for Use *(Describe)*
The EasyPoint® Blood Collection Plus is intended for use with evacuated blood collection tubes for venous blood collection, while aiding in the prevention of needlestick injuries and contaminated needle exposure.

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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K202325 510(k) SUMMARY
EASYPOINT® BLOOD COLLECTION PLUS
(21 CFR 807.92)

I. SUBMITTER

Retractable Technologies, Inc.
511 Lobo Lane
Little Elm, TX 75068

FDA Registration: 1647137

Phone: 972-294-1010

Fax: 972-294-4400

Contact Person: Becky Piroga, Regulatory Affairs Manager

Date Prepared: November 15, 2019

II. DEVICE

Name of Device: EasyPoint® Blood Collection Plus
Common Name: Blood collection tube holder with attached needle
Classification Name: -Tubes, vials, systems, serum separators, blood collection (21 CFR 862.1675)
Regulatory Class: II
Product Codes: JKA, FMI
510k Number: K202325

III. PREDICATE DEVICE K982541 – Vacutainer® Eclipse™ Blood Collection Needle

IV. DEVICE DESCRIPTION

The EasyPoint® Blood Collection Plus is a blood collection tube holder with an attached needle, and is intended to facilitate blood collection from patients. The device contains a sharps injury prevention feature (needlestick prevention feature - chamber, utilizing automated retraction technology) which covers the entire needle when activated. The EasyPoint® Blood Collection Plus aids in the prevention of needlestick injuries during normal handling and disposal, and prevents re-use of a contaminated needle.

The EasyPoint® Blood Collection Plus allows for multiple sample draws from a single venipuncture. After blood collection is complete, the retraction mechanism is activated and the device disassembles itself by retracting the contaminated needle into the safety chamber. The safety mechanism allows the user to activate the needle retraction while the needle is still in the patient, preventing exposure to the contaminated needle. The safety mechanism can be activated using one step and allows the user's hands to remain behind the sharp during activation.

V. INDICATIONS FOR USE

The EasyPoint® Blood Collection Plus is intended for use with evacuated blood collection tubes for venous blood collection, while aiding in the prevention of needlestick injuries and contaminated needle exposure.

The device contains a sharps injury prevention feature which covers the entire needle when activated. The safety mechanism allows the user to activate the needle retraction while the needle is still in the patient, preventing exposure to the contaminated needle.

VI. COMPARISON TO THE PREDICATE DEVICE

Feature	**Subject Device:** EasyPoint® Blood Collection Plus	**Predicate Device:** Vacutainer® Eclipse™ Blood Collection Needle	**Comparison**
Device Classification Name	Hypodermic single lumen needle	Hypodermic single lumen needle	Same
Regulatory Class	II	II	Same
FDA Product Code	JKA, FMI	FMI	Same, with additional category (blood collection)
Intended Use	Intended for use with evacuated blood collection tubes for venous blood collection, while aiding in the prevention of needlestick injuries and contaminated needle exposure.	Designed for use with Vacutainer® Blood Collection Needle Holders in performing venipuncture to obtain blood samples.	Same, except the EasyPoint® Blood Collection Plus is already attached to a blood collection tube holder (no need for a separate accessory device). *Comparison tests were performed using Vacutainer® Eclipse™ Blood Collection Needle with Pre-attached Holder.
Indications for Use	May be used for blood collection for diagnostic purposes of any patient population with consideration given to patient size, per institutional protocol. Single Use Only. Supplied Sterile.	May be used for blood collection for diagnostic purposes. Recommends referring to institutional protocol for venipuncture procedures; does not restrict usage to a particular patient population. Single Use Only. Supplied Sterile.	Same. Neither provides criteria for population-specific use of the product. Both products recommend referring to institutional protocol for appropriate venipuncture procedures. Both products are supplied sterile and are indicated for single use only. Both products are indicated for blood collection for diagnostic purposes.
Needle Gauge Size used in comparison studies	21G x 1 ¼"	21G x 1 ¼"	Same
Additional Needle Gauge Sizes Available	22G x 1 ¼"	22G x 1 ¼"	Same

Materials for Components in Common	*Needle Cap*: Polypropylene *Needle Cannula*: 304 Stainless Steel *Needle Lubricant*: Silicone Lubricant *Needle Adhesive*: UV Cure Adhesive *Needle Holder*: Polycarbonate *Needle Rubber Sleeve*: Synthetic Polyisoprene Rubber (not made with natural rubber latex) *Tube Holder*: Polypropylene	*Needle Cap*: Polypropylene *Needle Cannula*: 304 Stainless Steel *Needle Lubricant*: Silicone Lubricant *Needle Adhesive*: Epoxy Resin *Needle Holder*: Polystyrene *Needle Rubber Sleeve*: Synthetic Rubber (not made with natural rubber latex) *Tube Holder**: Polypropylene	Same except for needle holder and needle adhesive.
Materials for Components that Differ	*Retraction Spring:* 304 Stainless Steel *Device Body*: Polypropylene *Tube Holder Connector*: Polypropylene	*Collar:* Polystyrene *Safety Shield*: Polypropylene	N/A
Safety Mechanism	Automated Retraction Technology	Hinged Safety Shield	The EasyPoint® Blood Collection Plus utilizes a retraction safety mechanism, which retracts the contaminated needle into a safety chamber using automated retraction technology. The Vacutainer® Eclipse™ Blood Collection Needle utilizes a safety shield safety mechanism, which covers the contaminated needle after use using a hinged safety shield activated with thumb pressure.
Sterilization Method	Ethylene Oxide	Radiation	The sterilization methods are different, but both provide the same level of sterility assurance. Both products, through validated sterilization methods to their respective ISO standards (ISO 11135 and ISO

			11137), guarantee a SAL of 10^{-6}.
Biocompatibility	ISO 10993-1 Cytotoxicity, etc [list tests]	ISO 10993-1	Same. Both products conform to ISO 10993-1, Biological evaluation of medical devices – Evaluation and testing within a risk management process.
Precautions and Symbols Indicated on Packaging	-Sterile (EO) -Do not re-use -Do not use if package is damaged -Not Made With Natural Rubber Latex -LOT number -Expiration Date -Non-toxic -Non-pyrogenic -Consult instructions for use	-Sterile (R) -Do not re-use -Do not use if package is damaged -Not Made With Natural Rubber Latex -LOT number -Expiration Date -Keep away from sunlight -Caution	Similar. Biocompatibility and cytotoxicity testing has been performed by Retractable Technologies, Inc. to validate the claims of Non-toxic and Non-pyrogenic.

Additional information on performance and material comparison studies can be found in the body of this submission.

VII. PERFORMANCE DATA

Biocompatibility Testing

A Biological Safety Evaluation (BSE) of the EasyPoint® Blood Collection Plus was conducted in accordance with ISO 10993-1, ISO 14971, and the FDA Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1." It was found to be non-cytotoxic, a non-sensitizer, a non-irritant, non-pyrogenic, non-hemolytic, and to not produce acute systemic toxicity. Additional details and reports can be found in the body of this submission.

Mechanical Testing

Engineering and performance testing on the EasyPoint® Blood Collection Plus was performed according to applicable design requirements of ISO 7864 and ISO 9626. Performance tests were developed by Retractable Technologies, Inc. to measure the functionality (retraction) force, needle pullout force, rubber sleeve pullout force, needle cap separation force, puncture/penetration force, and to verify that the device does not leak under pressure. Additional details and reports can be found in the body of this submission.

Simulated Use Study

A simulated use pre-market study was conducted to demonstrate through human factors validation testing that the EasyPoint® Blood Collection Plus device performs safely and effectively when used by a variety of healthcare workers in a simulated use scenario. The study showed that the EasyPoint® Blood Collection Plus is comparable to currently legally marketed blood collection tube holders with regards to safety, ease of use, effective use, needlestick prevention, and device functionality. Additional details, including the final report from the pre-market study, can be found in the body of this submission.

Sterilization Validation

Sterilization validation was performed according to ISO 11135 – "Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices." The sterilization chamber and process used to sterilize the EasyPoint® Blood Collection Plus has been successfully used for many other products manufactured by Retractable Technologies, Inc. This re-validation to specifically address the addition of the EasyPoint® Blood Collection Plus demonstrated that the sterilization process continues to be effective and to meet the sterility assurance level (SAL) of 10^{-6}. Additional details and reports can be found in the body of this submission.

VIII. CONCLUSION

Results of testing have demonstrated that the EasyPoint® Blood Collection Plus meets requirements for its intended use. The EasyPoint® Blood Collection Plus is substantially equivalent to its predicate device, the Vacutainer® Eclipse™ Blood Collection Needle. The intended uses are the same, the materials are effectively the same, and no new concerns regarding safety and effectiveness were raised during comparison testing.