January 13, 2023

Medipoint Holdings, LLC
Rochelle Stern
Managing Partner
72 East 2nd St.
Mineola, New York 11501

Re: K223480
Trade/Device Name: Medipoint Blood Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: November 18, 2022
Received: November 18, 2022

Dear Rochelle Stern:

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,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K223480

Device Name
Medipoint Blood Lancets

Indications for Use *(Describe)*
Medipoint Blood Lancets are indicated to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.

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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K223480 – 510(k) Summary

Date Prepared:

01/13/2023

Submitted By:

Medipoint Holdings, LLC

72 East 2nd Street

Mineola, NY 11501

Contact:

Name: Rochelle Stern

Title: Managing Partner

Telephone: 516-294-8822

Email: rochelle@medipoint.com

Device:

Trade Name:	Medipoint Blood Lancets
Common Name:	Blood Lancet
FDA Product Code:	QRK
Classification Name:	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature
510(k) Number:	K223480

Predicate Devices:

The device is substantially equivalent to the following predicate devices:

Primary Predicate:	Medipoint Blood Lancets (510(k)-Exempt prior to reclassification)
Secondary Predicate:	Facet Technologies LLC Facet 28G Universal Lancet (K221433)

Device Description:

Medipoint Blood Lancets are indicated to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.

Medipoint Blood Lancets are single-use only and are discarded into a sharps container immediately after use.

The Medipoint Blood Lancet is constructed from a single piece of stainless steel with a sharp, beveled tip for piercing the skin and a knurled grip for maintaining a secure grip on the lancet. Each Medipoint Blood Lancet is individually packaged in a paper package and sterilized in the package via a validated moist heat sterilization process.

Indications for Use:

Th Medipoint Blood Lancets are indicated to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.

Technological Characteristics and Performance Data (Predicate Comparison):

The device has equivalent design, intended use, material performance, and biocompatibility compared to the predicate devices.

The device has equivalent non-clinical performance as the primary predicate device.

A comparison of technological characteristics and performance data to the predicate devices is provided in **Table 1**, below.

Table 1: Comparison to Predicate Devices

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
Applicant	Medipoint Holdings, LLC	Medipoint Holdings, LLC	Facet Technologies LLC	N/A
Product/Trade Name	Medipoint Blood Lancets	Medipoint Blood Lancets	Facet 28G Universal Lancet	N/A
Common Name	Blood Lancet	Blood Lancet	Blood Lancet	Same Common Name
Device Classification Name	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	Manual surgical instrument for general use	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature	Different device classification name compared to primary predicate due to reclassification order. However, the device is identical. Same classification name as secondary predicate.
510(k) Number	K223480	N/A, 510(k)-exempt	K221433	N/A
Classification Regulation	21 CFR 878.4850	21 CFR 878.4800	21 CFR 878.4850	Different classification regulation compared to primary predicate due to reclassification order. However, the device is identical. Same classification regulation as secondary predicate.
Product Code	QRK	FMK	QRK	Different product code compared to primary predicate due to reclassification order. However, the device is identical. Same product code as secondary predicate.
Intended Use	Medipoint Blood Lancets are indicated to obtain a capillary blood sample from the fingertip for	Medipoint Blood Lancets are intended for use to puncture the skin to obtain	The Facet 28G Universal Lancet is intended to perform a skin puncture of a finger or alternate site	The subject device is intended for the same use as the primary predicate device and similar intended use

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
	testing utilizing small amounts of blood. Medipoint Blood Lancets are single-use only.	a drop of blood for diagnostic purposes. Medipoint Blood Lancets are single-use only.	(palm of the hand, upper arm, or forearm) for collection of a droplet of capillary blood for subsequent diagnostic testing. The Lancet may be used in combination with a reusable lancet base (lancing device) that accepts a universal-type lancet to perform a lancing event. The Facet 28G Universal Lancet is for single use only on an individual patient.	compared to the secondary predicate device.
Indications for Use	Medipoint Blood Lancets are indicated to obtain a capillary blood sample from the fingertip for testing utilizing small amounts of blood.	Medipoint Blood Lancets are indicated for fingertip blood sampling for diagnostic purposes.	The Facet 28G Universal Lancet is a sterile, disposable single use device used to obtain a droplet of capillary blood for subsequent diagnostic testing from the finger or an alternative site, such as the palm, upper arm, or forearm. The Lancet is to be properly disposed of after a single use on an individual child, adolescent, or adult patient in a home setting.	There are minor differences in the indications for use statement between the subject device the predicate devices but the indications for use are substantially equivalent.
Sterility	Sterile (Moist Heat)	Sterile (Moist Heat)	Sterile (Gamma Irradiation)	Identical sterilization process and parameters compared to the primary predicate. While the sterilization

Product Characteristic	Subject Device	Primary Predicate	Secondary Predicate	Substantial Equivalence
				method is difference from the secondary predicate, both are provided sterile.
Type of Use	Over-The-Counter	Over-The-Counter	Over-The-Counter	Identical.
Device Dimensions	1 5/8" Long, 15/64" Wide, 0.007" Thick (0.025 – 0.032" Thick with knurls)	1 5/8" Long, 15/64" Wide, 0.007" Thick (0.025 – 0.032" Thick with knurls)	Needle: 3.1±0.45 mm Body: length not disclosed in 510(k) summary	Device dimensions are identical to the primary predicate.
Maximum Penetration Depth	7/64 inch (2.78 mm) ± 1/64 inch (0.40 mm)	7/64 inch (2.78 mm) ± 1/64 inch (0.40 mm)	3.1±0.45 mm	Similar, the Medipoint Blood Lancet maximum penetration is less than the secondary predicate.
Materials of Construction	430 Stainless Steel	430 Stainless Steel	304 Stainless Steel needle with low density polyethylene body	Materials of construction are identical to the primary predicate. The subject device material and needle portion of the secondary predicate are both constructed of stainless steel.
Tip Configuration	Bevel	Bevel	Bevel	Substantially equivalent, all devices have a beveled point.
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Substantially equivalent, the subject device has undergone biocompatibility testing in accordance with ISO 10993-1 based on the intended nature and duration of contact.

Non-Clinical Testing:

Non-clinical testing performed for the Medipoint Blood Lancets includes testing performed to ensure that predetermined performance criteria and conformance to special controls (21 CFR 878.4850) were met.

Performance Testing

The Medipoint Blood Lancets are constructed from a single piece of stainless steel and have no moving parts, joints, or caps which require mechanical testing. Performance testing completed for the Medipoint Blood Lancets demonstrates that the device withstands the forces encountered during use without bending or damage.

Biocompatibility Testing

Biocompatibility testing was selected based on ISO 10993 and the nature of device contact. The following biocompatibility tests were performed with passing results:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity (Material-Mediated Pyrogenicity)

All biocompatibility testing passed and demonstrates an acceptable biocompatibility profile for the intended nature and duration of contact of this device.

Conclusions:

The subject device and the predicate devices underwent evaluation for equivalence in the intended use of each device, biocompatibility, performance, environment of use, and the principles of operation. This evaluation demonstrates that the subject device is substantially equivalent to the predicate devices.