June 3, 2022

Ascensia Diabetes Care U.S., Inc.
Sangram Yadav
Regulatory Affairs Manager
5 Wood Hollow Road
Parsippany, New Jersey 07054

Re: K220633
Trade/Device Name: MICROLET NEXT Lancing Device, MICROLET Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: May 6, 2022
Received: May 9, 2022

Dear Sangram Yadav:

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,

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)*
K220633

Device Name
The MICROLET® lancet and MICROLET® NEXT lancing device

Indications for Use *(Describe)*
The MICROLET®NEXT lancing device is intended for collecting capillary blood from the fingertip or palm for blood glucose testing or other testing utilizing small amounts of blood. The MICROLET NEXT lancing device is for single-patient use. The MICROLET NEXT lancing device is used with disposable, sterile MICROLET® lancets. The MICROLET NEXT lancing device with the MICROLET lancet are intended for collecting fingertip capillary blood from persons age two years and older. The alternative site testing endcap is intended for collecting capillary blood from the palm in adults 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 for MICROLET® NEXT lancing device and MICROLET® Lancet

Initial date prepared: March 02, 2022
Revised date: May 25, 2022

According to the requirements of 21 CFR 807.92, the following information is being submitted in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence.

1. Submitter:
   Ascensia Diabetes Care U.S., Inc
   5 Wood Hollow Rd
   Parsippany, NJ 07054

   Contact:
   Sangram Yadav
   Regulatory Affairs Manager
   5 Wood Hollow Rd
   Parsippany, NJ 07054
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   Alternate Contact:
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   Head, Pre-Market Regulatory Affairs
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   Phone: +19142668530
   E-mail: brian.truchan@ascensia.com
2. Device name: MICROLET® Lancet and MICROLET® NEXT lancing device
   Classification name: Multiple Use Blood Lancet For Single Patient Use Only
   FDA CDRH review panel: General & Plastic Surgery
   Product Code: QRL
   Device Class: Class II
   Premarket review: Surgical and Infection Control Devices (OHT4)
   General Surgery Devices (DHT4A)
3. Predicate device: MICROLET® Lancet/MICROLET® NEXT lancing device (Class I, 510(k)-exempt blood lancets and lancing device legally offered for sale on or before November 22, 2021).
4. Device description:
   Ascensia's blood lancets consists of two components. First component is a re-usable base which is referred as MICROLET® NEXT lancing device and the second component is a sterile single use blade which is referred as MICROLET® Lancet. The subject

MICROLET® NEXT lancing device and MICROLET® Lancet falls under multiple Use Blood Lancet For Single Patient Use Only category. The subject MICROLET® NEXT Lancing Device is a pen-like instruments to be used with the compatible subject MICROLET® NEXT Lancets (28 G) for the controlled puncture of the skin to obtain the capillary blood droplet sample for testing. The MICROLET® NEXT Lancing Device is available with two endcaps: the Black/White cap for fingertip sampling and the Clear Alternative Site Testing (AST) for palm sampling. The Black/White cap has a dial control that allows the user to adjust the blade penetration depth for comfort when obtaining the blood droplet. The subject MICROLET® Lancet is a disposable single-use sterile device intended for drawing a blood sample. It is intended to be used with compatible lancing devices. The lancets are sterile, single-use devices. They must be discarded after each use. The lancet comprises the following elements: a steel needle, needle body with a protective cap. The lancet remains sterile until the cap is removed. The product is sterilized with gamma radiation. They are available with 28G (0.36mm) diameter lancets. Together, they are intended for obtaining a capillary blood sample for blood glucose testing or other testing utilizing small amounts of blood. The lancet needle consists of stainless steel which is coated with medical grade silicone for smooth penetration of the skin. The lancet needle is siliconized. This is encased in a plastic cover. The proposed MICROLET® Lancets are offered in a variety of colors. Figure-2 shows different colored lancets (seven colors-Yellow, Orange, Red, Green, Blue, Purple and Pink). The needle tip is hidden by a protective cap, which has to be removed before usage and creates the sterile barrier. After usage the lancet can be placed back into the protective cap for disposal, thereby protecting users from unintended injuries. The proposed MICROLET® Lancet can be stored for 5 years without losing its function or sterility if the protective cap is not removed. The MICROLET® Lancet is a disposable single-use sterile device intended for drawing a blood sample. It is Intended to be used with compatible lancing device. The lancet comprises the following elements: a steel needle, needle body with a protective cap. The lancet remains sterile until the cap is removed. The product is sterilized with gamma radiation. The product can be stored for 5 years without losing its function or sterility if the protective cap is not removed. The MICROLET® NEXT lancing device is used for obtaining capillary blood samples from the fingertip. Capillary samples can be obtained from the palm as well The lancing device is for use only on a single patient.

5. Indications for Use: The MICROLET®NEXT lancing device is intended for collecting capillary blood from the fingertip or palm for blood glucose testing or other testing utilizing small amounts of blood. The MICROLET NEXT lancing device is for single-patient use. The MICROLET NEXT lancing device is used with disposable, sterile MICROLET® lancets. The MICROLET NEXT lancing device with the MICROLET lancet are intended for collecting fingertip capillary blood from persons age two years and older. The alternative site testing endcap is intended for collecting capillary blood from the palm in adults only.

6. Substantial Equivalence:

Technological similarities and differences are as follows:

Table 1.1 Comparison between predicate MICROLET® Lancet; MICROLET® NEXT lancing device (510(k)-exempt), and proposed device MICROLET® Lancet MICROLET® NEXT lancing device (up-Classified)

No	Feature	Predicate Device MICROLET® Lancet MICROLET® NEXT lancing device (Class I, 510(k)-exempt)	Proposed Device MICROLET® Lancet MICROLET® NEXT lancing device (Class II)	Similarities/ Differences
1	Classification	Class I Product Code: FMK Regulation: 21 CFR 878.4850	Class II Product Code: QRL Regulation: 21 CFR 878.4850	Different
2	Subtype	Multiple Use Blood Lancet For Single Patient Use Only	Multiple Use Blood Lancet For Single Patient Use Only	Same
3	Type of Use	Over the Counter use	Over the Counter use	Same
4	Indications for Use	The MICROLET® NEXT lancing device is intended for collecting capillary blood from the fingertip or palm for blood glucose testing or other testing utilizing small amounts of blood. The Microlet Next lancing device is for single-patient use. The Microlet Next lancing device is used with disposable, sterile MICROLET® lancets. The Microlet Next lancing device with the Microlet lancet are intended for collecting capillary blood persons age two years and older.	The MICROLET®NEXT lancing device is intended for collecting capillary blood from the fingertip or palm for blood glucose testing or other testing utilizing small amounts of blood. The MICROLET NEXT lancing device is for single-patient use. The MICROLET NEXT lancing device is used with disposable, sterile MICROLET® lancets. The MICROLET NEXT lancing device with the MICROLET lancet are intended for collecting fingertip capillary blood from persons age two years and older. The alternative site testing endcap is intended for	Different. The alternative site testing endcap is intended for collecting capillary blood from the palm in adults only.

Table 1.1 Comparison between predicate MICROLET® Lancet; MICROLET® NEXT lancing device (510(k)-exempt), and proposed device MICROLET® Lancet MICROLET® NEXT lancing device (up-Classified)				
No	**Feature**	**Predicate Device MICROLET® Lancet MICROLET® NEXT lancing device (Class I, 510(k)-exempt)**	**Proposed Device MICROLET® Lancet MICROLET® NEXT lancing device (Class II)**	**Similarities/ Differences**
			collecting capillary blood from the palm in adults only.	
5	Anatomical Location in the Body	Fingertip or ATS (palm)	Fingertip or ATS (palm)	Same
6	Patient Population	persons age two years and older.	persons age two years and older. The alternative site testing endcap is intended for collecting capillary blood from the palm in adults only.	Different
7	Intended User	Persons of different ages diagnosed with Diabetes; can also be used by caregivers or family members who support an individual with Type1 and Type 2 diabetes.	Persons of different ages diagnosed with Diabetes; can also be used by caregivers or family members who support an individual with Type1 and Type 2 diabetes.	Same
8	Protective cover of the lancet	Protective cap is used to push the used lancet into the center in order to avoid injuries.	Protective cap is used to push the used lancet into the center in order to avoid injuries.	Same
9	Compatibility of Lancing	Compatible with Microlet® Next lancing device	Compatible with Microlet® Next lancing device	Same

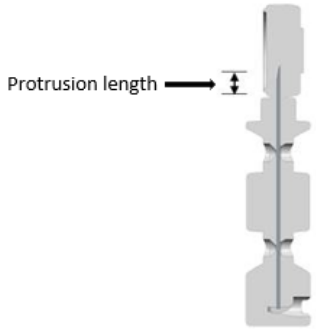
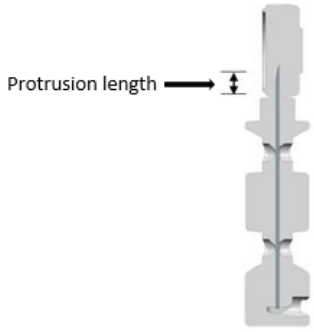
Table 1.1 Comparison between predicate MICROLET® Lancet; MICROLET® NEXT lancing device (510(k)-exempt), and proposed device MICROLET® Lancet MICROLET® NEXT lancing device (up-Classified)				
No	**Feature**	**Predicate Device MICROLET® Lancet MICROLET® NEXT lancing device (Class I, 510(k)-exempt)**	**Proposed Device MICROLET® Lancet MICROLET® NEXT lancing device (Class II)**	**Similarities/ Differences**
	device with Lancets			
10	Dimensions/Size	Lancets(Blade): Size 28 G(Gauge) length: 32.3 mm width: 9.25 mm depth: 6.45 mm	Lancets(Blade): Size 28 G(Gauge) length: 32.3 mm width: 9.25 mm depth: 6.45 mm	Same
		Lancing device(reusable base): 102.5 x 19 x 20 mm	Lancing device(reusable base): 102.5 x 19 x 20 mm	
11	Protrusion Length of needle(lancets)	3.25 ±0.3 mm  Note- Protrusion Length of needle is the length of the exposed needle from the lancet body, after the protective cap is removed.	3.25 ±0.3 mm  Note- Protrusion Length of needle is the length of the exposed needle from the lancet body, after the protective cap is removed.	Same
12	Depth settings	5 depth settings	5 depth settings	Same

Table 1.1 Comparison between predicate MICROLET® Lancet; MICROLET® NEXT lancing device (510(k)-exempt), and proposed device MICROLET® Lancet MICROLET® NEXT lancing device (up-Classified)

No	Feature	**Predicate Device** MICROLET® Lancet MICROLET® NEXT lancing device (Class I, 510(k)-exempt)	**Proposed Device** MICROLET® Lancet MICROLET® NEXT lancing device (Class II)	**Similarities/ Differences**
13	Penetration depth	Alternative site testing endcap: 3.33 mm. Adjustable cap: Setting / Puncture Depth(mm) 1 / 1.25 2 / 1.65 3 / 2.00 4 / 2.38 5 / 2.75 The difference between each depth level is 0.4 mm or less.	Alternative site testing endcap: 3.33 mm. Adjustable cap: Setting / Puncture Depth(mm) 1 / 1.25 2 / 1.65 3 / 2.00 4 / 2.38 5 / 2.75 The difference between each depth level is 0.4 mm or less.	Same
14	Duration of Body Contact	Transient, less than 1 minute	Transient, less than 1 minute	Same
15	Use(Sing-le patient)	Single use Sterile lancets	Single use Sterile lancets	Same
16	Use(lancing devices)	Reusable. The lancing device is for use only on a single patient.	Reusable. The lancing device is for use only on a single patient	Same
17	Sterilization method and SAL	Sterilized by Radiation SAL=10 -6	Sterilized by Radiation SAL=10 -6	Same

Table 1.1 Comparison between predicate MICROLET® Lancet; MICROLET® NEXT lancing device (510(k)-exempt), and proposed device MICROLET® Lancet MICROLET® NEXT lancing device (up-Classified)				
No	**Feature**	**Predicate Device MICROLET® Lancet MICROLET® NEXT lancing device (Class I, 510(k)-exempt)**	**Proposed Device MICROLET® Lancet MICROLET® NEXT lancing device (Class II)**	**Similarities/ Differences**
18	Shelf life	Lancets- 5 years	Lancets- 5 years	Same
19	Use life	Lancing device 3 years	Lancing device 2 years	Different
20	disinfection frequency	Once a week	After each use	Different

7. Summary of Non-Clinical Performance Data
Biocompatibility: Cytotoxicity,Inctracutaneous, Systemic Toxicity, Hemolysis, Sensitization and Pyrogen testing was performed on all patient contacting materials lancet and lancing device in accordance with FDA Guidance document Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process (summarized in below table). All patient contact components demonstrated biocompatibility.

Table 1.2 Biocompatibility testing standards and results for the proposed MICROLET® Lancet and MICROLET® lancing device			
No	**Test**	**Standard**	**Results**
1	Cytotoxicity Study - ISO Elution Method	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic
2	ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-sensitizer

Table 1.2 Biocompatibility testing standards and results for the proposed MICROLET® Lancet and MICROLET® lancing device			
No	**Test**	**Standard**	**Results**
3	ISO Intracutaneous Study in Rabbits	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-irritant
4	Material Mediated Pyrogenicity in Rabbits	ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Non-pyrogenic
5	ISO Acute Systemic Toxicity	ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	Non-toxic
6	ASTM Hemolysis Study	ISO 10993-4:2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	Non-hemolytic
Biocompatibility testing for MICROLET® lancing device			
7	Cytotoxicity Study - ISO Elution Method	ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic
8	ISO Guinea Pig Maximization Sensitization Test	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-sensitizer
9	ISO Intracutaneous Study in Rabbits	ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-irritant
Note- MICROLET® NEXT lancing device, including adjustable (ABS) and Alternate Site Testing (AST) (Polycarbonate) caps; subject to this premarket notification is identical to the previously legally US-marketed (510k exempt) device in formulation, processing, sterilization, and geometry, and no other chemicals have been added.			

8. Performance Testing

The following Performance testing were conducted to demonstrate the basic performance of MICROLET® Lancet and lancing device and confirmed that the MICROLET® Lancet and lancing device performs as intended.

Table 1.3 Performance testing for the proposed MICROLET® Lancet and MICROLET® NEXT lancing device		
No	**Test**	**Results**
1	Vibration Testing	**Pass** There was no external damage or deterioration noted to any of the devices tested.
2	Ejector Arm remove force	**Pass** The Ejector arm force results for all devices were within the acceptance range.
3	Endcap Assembly removal and install torque verification	**Pass** Both the install and removal torque mean values were well within acceptable criteria.
4	Lancet Ejection force	**Pass** All device results were within the acceptance range.
5	Lancet insertion force	**Pass** All device results were within the acceptance range.
6	Priming force verification	**Pass** All device results were within the acceptance range.
7	Puncture Depth Setting verification	**Pass** All device results were within the acceptance range.
8	Trigger button actuation force	**Pass** All device results were within the acceptance range.
9	Device Size verification	**Pass** All device results were within the acceptance range.
10	Lancet Anti Rotation torque	**Pass** All device results were within the acceptance range.
11	Puncture setting torque	**Pass** All device results were within the acceptance range.
12	Solution Compatibility reliability testing	**Pass** All device results were within the acceptance range.
13	Reliability Testing Mechanical vibration free fall drop	**Pass** All devices meet the visual , functional and performance acceptance criteria relevant to test requirements.
14	High speed Camera Analysis	**Pass** All device data results were within acceptance criteria.
15	Corrosion Resistance testing	**Pass** After the test no corrosion was noticed on any of the product parts.
16	Dry heat storage test-Extreme heat	**Pass**

Table 1.3 Performance testing for the proposed MICROLET® Lancet and MICROLET® NEXT lancing device		
No	**Test**	**Results**
		After the test no damage to the functionality of the device was noticed.
17	Dry heat Storage test	**Pass** After the test no damage to the functionality of the device was noticed.
18	Mechanical vibration test	**Pass** All device data results were within acceptance criteria.
19	Thermal Shock	**Pass** All device data results were within acceptance criteria
20	AST needle tip flush verification test	**Pass** All devices met the min 1.3 mm needle tip distance.
21	Reliability Retail Carton Free Fall Drop Report	**Pass** All devices met tested in the retail carton kit meet the acceptance criteria.
22	Bulk Device shipping test	**Pass** No damages were observed to the content after the test.
23	Shipping Simulation testing	**Pass** All device packaging passed the shipping simulations testing.
24	Human factor	**Pass** The MICROLET® Lancet and MICROLET® NEXT lancing device human factors validation testing was conducted to demonstrate the device can be used by people with diabetes without serious use errors or problems under the expected use conditions. The summative evaluation concluded the system is safe and effective for at-home use by people with diabetes.

8. Clinical Testing:

A total of 119 lay persons who had never used the proposed MICROLET® Lancet and MICROLET® NEXT lancing device previously were enrolled into the study at the Mishawaka site, and 119 completed the study.

- 119 adult subjects were able to obtain sufficient capillary blood volume from fingertips to conduct blood glucose testing, by using the adjustable cap.
- 116 adult subjects were able to obtain sufficient capillary blood volume from the palm to conduct blood glucose testing, by using the AST(Alternative site testing endcap.

The demographics and diabetes history information for all subjects enrolled in the study (n=119) included the following:

- 22% (26) reported they had type 1 diabetes; 76% (90) had type 2 diabetes and 3% (3) had diabetes but did not know their diabetes type
- The average (mean) age was 55.1 years (with a range of 23 to 84 years).
- 80.7% (96) of subjects were less than age 65 years

Below is the demographic information for subjects:

Gender: Female 61(51.3%); Male 58(48.7%)

Ethnicity: Hispanic/Latino 3(2.5%); Non-Hispanic 110(92.4%); not reported 6(5.0%)

Race: Asian 1(0.8%), African American 14(11.8%), Caucasian 99(83.2%), American Indian/Alaskan Native 3(2.5%), Wish to not report 3(2.5%).

Following was the inclusion/exclusion criteria for the clinical study:

Inclusion Criteria:

- Males and females, 18 years of age and older
- People with type 1 or type 2 diabetes
- People who regularly perform self-tests (at least once/day) with their own lancing device
- Able to speak, read and understand English (subjects must demonstrate ability to read a paragraph from the first page of the Informed Consent document to qualify for the study)
- Willing to complete all study procedures

Exclusion Criteria:

- Those with missing tips of the fingers indicated numerically or are physically unable to lance the palm areas and all 6 of the fingers
- Hemophilia or any other bleeding disorder
- Pregnancy
- Physical, visual or neurological impairments that would make the person unable to perform, testing. Subjects who have used the proposed lancing device in a previous clinical evaluation

Adverse Events: One (1) adverse event of hypoglycemia was reported. This was a non-serious, mild, anticipated, non-device related Adverse Event (AE). The event was resolved prior to the subject leaving the clinical site.

Conclusion- The acceptability of capillary blood volume obtained using the adjustable fingerstick and alternative site testing endcap by lay users with diabetes, was determined by study staff testing the blood on a Contour next family of blood glucose meters. Performance was analyzed using the percentage of numeric vs non-numeric meter readings obtained. All primary and secondary objectives of the clinical study were met.

9. Conclusion Regarding Substantial Equivalence

The proposed MICROLET® NEXT lancing device is intended for collecting capillary blood from the fingertip or palm for blood glucose testing or other testing utilizing small amounts of blood. The Microlet Next lancing device is for single-patient use. The Microlet Next lancing device is used with disposable, sterile MICROLET® lancets. The Microlet Next lancing device with the Microlet lancet are intended for collecting capillary blood from persons age two years and older. The alternative site testing endcap is intended for collecting capillary blood from the palm in adults only.

The proposed MICROLET® Lancet/ MICROLET® NEXT lancing device has the similar intended use, incorporate the same fundamental technology as the predicate MICROLET® Lancet/ MICROLET® NEXT lancing device which were previously 510 (k) exempt. The differences between 510(k)-exempt MICROLET® Lancet/ MICROLET® NEXT lancing device (legally offered for sale on or before November 22, 2021) and up classified MICROLET® Lancet lancing device do not raise any new questions of safety, or effectiveness. Test data to verify the performance of the up classified MICROLET® Lancet/lancing device has been provided including: biocompatibility, Sterility, clinical and non-clinical performance testing and the results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.