May 14, 2025

Ascensia Diabetes Care US Inc
Sangram Yadav
Regulatory Affairs Manager, US
5 Wood Hollow Rd
Parsippany, New Jersey 07054

Re: K250813
Trade/Device Name: MICROLET®NEXT 2 Lancing Device
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: March 17, 2025
Received: March 17, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 H. Jang -S
Digitally signed by James H. Jang -S
Date: 2025.05.14 14:33:25 -04'00'

James Jang, Ph.D.
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250813

Please provide the device trade name(s).

MICROLET®NEXT 2 Lancing Device

Please provide your Indications for Use below.

The MICROLET®NEXT 2 Lancing Device is used with the disposable MICROLET®NEXT Lancet to obtain capillary blood samples.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K250813

510(k) Summary

Prepared on: 2025-05-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ASCENSIA DIABETES CARE US INC
Applicant Address	5 WOOD HOLLOW RD Parsippany NJ 07054 United States
Applicant Contact Telephone	2019368856
Applicant Contact	Mr. SANGRAM YADAV
Applicant Contact Email	sangram.yadav@ascensia.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MICROLET®NEXT 2 Lancing Device
Common Name	Blood lancets
Classification Name	Multiple Use Blood Lancet For Single Patient Use Only
Regulation Number	878.4850
Product Code(s)	QRL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221970	STERILANCE LANCING DEVICE	QRL

Device Description Summary

21 CFR 807.92(a)(4)

The proposed MICROLET®NEXT 2 Lancing Device falls under multiple Use Blood Lancet for Single Patient Use Only category. The proposed MICROLET®NEXT 2 Lancing Device is a pen-like instruments to be used with the compatible MICROLET® NEXT Lancets (28 G) for the controlled puncture of the skin to obtain the capillary blood droplet sample for testing. Please refer to the attachments for more detail device description, pictures and packaging.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The MICROLET®NEXT 2 Lancing Device is used with the disposable MICROLET®NEXT Lancet to obtain capillary blood samples.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed MICROLET® NEXT 2 Lancing Device has same indication for use as the predicate Sterilance Lancing Device(Class II, Product Code : QRL 510(k) K221970).

Technological Comparison

21 CFR 807.92(a)(6)

The proposed MICROLET® NEXT 2 Lancing Device has the same contract manufacture and same fundamental technological characteristics as the predicate Sterilance Lancing Device (Class II, Product Code: QRL 510(k) K221970)., except for the changes requested by ADC as the spec developer. These differences are identified in the comparison table in the substantial equivalence section.

The primary difference is proposed MICROLET® NEXT 2 Lancing Device can be disinfected after each use and therefore has a different use

life (3 years) compared to predicate Sterilance Lancing Device (Class II, Product Code : QRL 510(k) K221970) which is disinfected once a week and has use life of 5 years.

Also, the proposed MICROLET® NEXT Lancing Device has different Colors (Gray, Black, White) and AST penetration depth 2.45 ± 0.55 (1.9-3.0 mm) which is tighter in specifications, as compared to predicate Sterilance Lancing Device Colors (Gray, White, Orange) and wider AST penetration depth ≥1.1 i.e. (1.1 - 3.0 mm).

Differences such as Color, tighter AST penetration depths, different use life's and different frequencies of disinfection between the proposed MICROLET® NEXT 2 lancing device and the predicate Sterilance Lancing Device (Class II, Product Code: QRL 510(k) K221970),are supported by bio compatibility, reprocessing validation, performance tests, usability testing and clinical study.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing and clinical study are included in this premarket notification to verify that any differences in technological characteristics of the proposed MICROLET® NEXT 2 Lancing Device and the predicate Sterilance Lancing Device (Class II, Product Code: QRL 510(k) K221970) do not raise new questions of safety and effectiveness.

Summary of Clinical Testing:
A total of 131 lay persons with diabetes, who had never used the proposed MICROLET®NEXT 2 Lancing Device previously, were enrolled into the study at a single clinical site, and 120 completed the study.

The demographics for all subjects enrolled in the study included the following:
• 61.7% of subjects who were < 65 years old.
Below is the demographic information for subjects:
Ethnicity: Hispanic/Latino 16 (13.33%); non-Hispanic 104 (86.67%).
Race: Asian 5 (4.17%), African American 36 (30.0%), Caucasian 81 (67.50 %), American Indian/Alaskan Native 2 (2.5%), Wish to not report 1 (0.83%).
Gender: Female: 58(48.33%)
Male: 62 (51.67%).
Following were 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
• Persons who are currently or have previously used proposed MICROLET®NEXT 2 Lancing Device to perform, self-testing as part of routine blood glucose monitoring.
• 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:
• Hemophilia or any other bleeding disorder
• Pregnancy
• Physical, visual or neurological impairments that would make the person unable to perform testing.
• Significant skin impairments/scarring that would interfere with lancing in the opinion of the investigator or designee.
• Subjects who have used the proposed MICROLET®NEXT 2 Lancing Device in a previous clinical evaluation.
• A condition, which in the opinion of the investigator or designee, would put the person or study conduct at risk.
• Working for a competitive medical device company, or having an immediate family member or someone who is not a family member but is living within the household of someone who works for such a company

Clinical Testing Adverse Events: No adverse events were reported
Clinical Testing Results:
Subjects demonstrated that they could use the proposed MICROLET®NEXT 2 Lancing Device to obtain adequate blood volume from fingertip and palm lancing to obtain a numerical or non-numerical result on the BGMS(Blood Glucose Monitoring System), after reading the IFU to learn the basic operation of the system.

It is concluded that nonclinical and clinical tests demonstrate that the MICROLET® NEXT 2 Lancing Device is as safe, as effective, and performs as well as the predicate Sterilance Lancing Device (Class II, Product Code: QRL 510(k) K221970).

It is concluded that the information provided in this discussion supports substantial equivalence for the proposed MICROLET® NEXT 2 Lancing Device and the predicate Sterilance Lancing Device (Class II, Product Code: QRL 510(k) K221970).