August 15, 2024

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

Re: K241810
Trade/Device Name: MICROLET®NEXT Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK
Dated: June 20, 2024
Received: June 21, 2024

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.

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.08.15 13:25:38 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241810

Device Name

MICROLET®NEXT Lancet

Indications for Use *(Describe)*

The disposable MICROLET®NEXT Lancet is used for capillary blood collection.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared on: 2024-06-21

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 Lancet
Common Name	Blood lancets
Classification Name	Single Use Only Blood Lancet Without An Integral Sharps Injury Prevention Feature
Regulation Number	878.4850
Product Code(s)	QRK

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221507	STERILANCE DISPOSABLE BLOOD LANCET	QRK

Device Description Summary

21 CFR 807.92(a)(4)

The disposable MICROLET®NEXT Lancet is used for capillary blood collection. The device comprises of a stainless needle encapsulated with a plastic and protective cap; the protective cap is twisted off to expose the needle for use. The device is sterilized by radiation. The needle body and protective cap form a sterile barrier to maintain the needle sterile. Please refer to below attachments for detailed device description. pictures and packaging.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The disposable MICROLET®NEXT Lancet is used for capillary blood collection.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed MICROLET®NEXT Lancet has same indication for use as the predicate Sterilance Disposable Blood Lancet(Class II, K221507, Product code: QRK).

Technological Comparison

21 CFR 807.92(a)(6)

The proposed MICROLET®NEXT Lancet has the same fundamental technological characteristics as the predicate Sterilance Lancing Device (Class II, Product Code: QRL 510(k) K221970)., except for the following differences.
The primary difference is that proposed MICROLET®NEXT lancet is sold in one size (i.e.28 G limited to one size) and seven colors(Yellow, Orange, Red, Green, Blue, Purple and Pink) ; while predicate Sterilance Blood Lancets (Class II, K221507, Product code: QRK) are sold in additional sizes (28 G; other sizes such as 21G, 23G, 26G, 30G, 32G, 33G) and slightly different colors(Yellow, light blue, Pink, Dark blue,

Purple, Ivory yellow and Green). Additionally MICROLET®NEXT lancet has tighter dimensional specification within the range of predicate dimensions for exposed needle length.

Differences such additional sizes and slightly different colors (Yellow, light blue, Pink, Dark blue, Purple, Ivory yellow and Green) between the proposed MICROLET®NEXT Lancets and the predicate Sterilance Disposable Blood lancets (Class II, K221507, Product code: QRK) are supported by bio compatibility, Sterilization, performance tests, usability testing and clinical study.

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

Test data to verify the performance of the proposed MICROLET®NEXT Lancets including: bio-compatibility, usability, Shelf life, clinical study, and the results of these testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence. Performance testing is included in this premarket notification to verify that any differences in technological characteristics of the proposed MICROLET®NEXT Lancets and the predicate 510(k)cleared Sterilance Disposable Blood lancets do not raise new questions of safety and effectiveness. It is concluded that the information provided in this discussion supports substantial equivalence for the proposed the proposed MICROLET®NEXT Lancets and the predicate 510(k)cleared Sterilance Disposable Blood lancets.

Summary of Clinical Testing:
A total of 131 lay persons with diabetes, who had never used the proposed MICROLET®NEXT Lancet previously, were enrolled into the study at a single clinical site, and 120 completed the study. Subjects demonstrated that they could use the proposed MICROLET®NEXT Lancet 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 the information provided in this discussion supports substantial equivalence for the proposed the proposed MICROLET®NEXT Lancets and the predicate 510(k)cleared Sterilance Disposable Blood lancets.