January 25, 2024

Facet Technologies, LLC
James Bonds
Director Regulatory Affairs
3900 North Commerce Drive
Atlanta, Georgia 30344

Re: K232912
Trade/Device Name: Facet Aurora Reusable Lancet Base
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL
Dated: January 5, 2024
Received: January 5, 2024

Dear James Bonds:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2024.01.25 13:59:29 -05'00'

Mark Trumbore, 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)*
K232912

Device Name
Facet Aurora Reusable Lancet Base

Indications for Use *(Describe)*
The Facet Aurora Reusable Lancet Base (commonly referred to as a lancing device) is a non-sterile reusable device which provides a spring-loaded mechanism to quickly eject and retract a lancet of proprietary design to effect a lancing event for the purpose of obtaining a droplet of capillary blood for diagnostic testing in children, adolescents, and adults in a home setting.

The device is designed to be cleaned and disinfected between uses on a single patient.

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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K232912

Facet Aurora Reuseable Lancet Base

510(k) Summary
(Reference 21 CFR 807.92)

Submitted by:	Facet Technologies, LLC 3900 North Commerce Drive Atlanta, GA 30344-8149 Phone Number: (770) 590-6462 Fax Number: (770) 590-6412
Contact:	James R. Bonds Director Regulatory Affairs JBonds@facetmed.com
Date of Preparation:	January 5, 2024
Device Trade Name:	Facet Aurora Reuseable Lancet Base
Common Name:	Lancing Device
Classification Name:	Multiple use blood lancet base for single patient use only
Regulation:	878.4850
Product codes:	QRL (Multiple use blood lancet intended for use on a single patient use only)
Product Classification:	II
Panel:	General & Plastic Surgery
Predicate Device:	Facet Aurora Reuseable Lancet Base (Product Code MDM, 510(k) Exempt)

Device Description

The Facet Aurora Reuseable Lancet Base is a blood sampling device used in conjunction with a lancet blade of proprietary design to obtain a sample of capillary blood for diagnostic purposes, primarily for blood glucose monitoring in diabetic patients.

The lancing device has been in commercial distribution in the United States for over 10 years. There have been no significant design changes over the life of the device.

Indication for Use

The Facet Aurora Reusable Lancet Base (commonly referred to as a lancing device) is a non-sterile reusable device which provides a spring-loaded mechanism to quickly eject and retract a lancet of proprietary design to effect a lancing event for the purpose of obtaining a droplet of capillary blood for diagnostic testing in children, adolescents, and adults in a home setting.

The device is designed to be cleaned and disinfected between uses on a single patient.

Technological Characteristics

The primary technological characteristics and intended use of the Facet Aurora Reuseable Lancet Base are substantially equivalent to the predicate device.

As indicated in, the Facet Aurora Reuseable Lancet Base is substantially equivalent to characteristics of the identified predicate device, the Facet Aurora Reuseable Lancet Base previously marketed as a 510(k) exempt device.

As indicated in Table 1, the Facet Aurora Reuseable Lancet Base is substantially equivalent to characteristics of the identified predicate device, the Facet Aurora Reuseable Lancet Base previously marketed as a 510(k) exempt device.

Table 1: Comparison of Subject Device and Predicate Device

Characteristic	Predicate Device	Subject Device
Indication for Use	The Facet Aurora Reusable Lancet Base (commonly referred to as a lancing device) is a non-sterile reusable device which provides a spring-loaded mechanism to quickly eject and retract a lancet of proprietary design to effect a lancing event for the purpose of obtaining a droplet of capillary blood for diagnostic testing in children, adolescents, and adults in a home setting. The device is designed to be cleaned and disinfected between uses on a single patient.	Same
Manufacturer	Facet Technologies, LLC	Same
510(k) Number	N/A	K232912
Product Code	MDM	QRL
Sterility	Non-sterile, can be cleaned and low-level disinfected between uses	Same
Penetration Adjustment Depths	7 depth settings 0.5mm-2.75mm, with each change of the depth setting being approximately 0.3 mm	Same
Materials	Polycarbonate, ABS (acrylonitrile-butadiene-styrene), present separately and as copolymers	Same

Non-clinical Testing Summary and Conclusions

Non-clinical bench testing was performed to ensure predetermined criteria were met and the special controls (21 CFR 878.4850) were satisfied. This includes mechanical design verification and validation testing in order to ensure the risks were appropriately managed in addition to verifying that the mechanical functions of the device are suitable for use over the shelf life of the device.

Table 2: Summary of Nonclinical Tests Performed

Property/Characteristic	Test Method	Importance	Reference
Endcap Removal Force	Tensile strength tester	Ensure cap can be removed easily to insert lancet blade	N/A
Endcap Attachment Force	Tensile strength tester	Ensure cap will remain on lancet base during lancing event	N/A
Depth of Puncture	Calibrated High Speed Video	Ensure depth of puncture is repeatable for various depth settings	N/A
Over-Charging Force	Tensile force gauge	Ensure that device can be charged to engage actuation spring	N/A
Charging Force	Tensile force gauge	Ensure device can be charged to engage actuation spring	N/A
Lancet Insertion Force	Tensile force gauge	Ensure lancet can be easily inserted	N/A
Depth Adjust Torque	Torque gauge	Ensure that depth adjustment can be easily adjusted and that adjustment will not change during use	N/A
Button Activation Force	Tensile force gauge	Ensure activation force is within specification	N/A
Lancet Rotation	Torque gauge	Ensure lancet does not rotate during device actuation	N/A

Property/Characteristic	Test Method	Importance	Reference
Drop Test	Simulated Use after drop	Ensure that device can withstand a 1 meter drop to a hard surface and still function	N/A
Life Cycle Test	Simulated use	Ensure device can withstand 3 years of expected use	N/A
Chemical Test	Cleaning and disinfection studies	Ensure device can withstand recommended cleaning and disinfection over useful life	N/A
Storage Temperature Test	Simulated Use	Ensure device can function after exposure to heat and cold cycles	N/A
Biocompatibility	Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity, Acute Systemic toxicity (materials mediated pyrogen)	Ensure material of construction are biocompatible for their intended use	FDA Guidance *Use of International Standard 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", Sept. 2020*, ISO 10993-1, ISO 10993-5, ISO 0993-10, ISO 10993-11

In summary, the results of nonclinical testing demonstrate that the candidate device is substantially equivalent to the predicate device.

- **Conclusion**

The intended use, technology, non-clinical testing, and functionality of the Facet Aurora Reuseable Lancet Base demonstrate a substantially equivalent safety and effectiveness profile to the predicate device and should perform as well as the predicate in the specified use conditions.