July 15, 2022

Facet Technologies LLC
James Bonds
Director Regulatory Affairs
3900 N. Commerce Dr.
Atlanta, Georgia 30344

Re: K221433
Trade/Device Name: Facet 28G Universal Lancet
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRK, QRL
Dated: May 16, 2022
Received: May 17, 2022

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 (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

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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,

Colin K. Chen -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)*
K221433

Device Name
Facet 28G Universal Lancet

Indications for Use *(Describe)*
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.

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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Facet 28G Universal Lancet

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
Date of Preparation:	July 13, 2022
Device Trade Name:	Facet 28G Universal Lancet
Common Name:	Blood Lancet
Classification Name:	Single use only blood lancet without an integral sharps injury prevention feature
Regulation:	878.4850
Product codes:	QRK (Single use only blood lancet without an integral sharps injury prevention feature) QRL (Multiple use blood lancet for single patient use only)
Product Classification:	II
Panel:	General & Plastic Surgery
Predicate Device:	Facet 28G Universal Lancet (Product Code FMK, 510(k) Exempt)

Device Description

The Facet 28G Universal Lancet (Facet Lancet) is a sterile, single use, blood sampling device used to obtain a sample of capillary blood for diagnostic purposes, primarily for blood glucose monitoring in diabetic patients.

The predicate device has been in commercial distribution since 2006.

Facet lancets are intended to be used by diabetic patients to obtain a blood sample for assistance in self-monitoring of their blood glucose levels. The lancets consist of a 28G stainless steel needle overmolded with low density polyethylene (LDPE) and integral sterility cap. The lancet is single use, disposable and is sterilized by gamma radiation to a SAL of 10^{-6}.

The predicate device is currently in commercial distribution in the United States, European, and other worldwide markets. Since commercial distribution of the current lancets began, there have been no design changes.

Indications for Use

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.

Technological Characteristics

The primary technological characteristics and intended use of the Facet 28G Universal Lancet are substantially equivalent to the predicate device.

As indicated in Table 1, the Facet 28G Universal Lancet is substantially equivalent to characteristics of the identified predicate device, the Facet 28 G Universal Lancet 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 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.	Same
Intended Use	The Facet 28G Universal Lancet is intended to perform a skin puncture of a finger or alternate site (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.	Same
Manufacturer	Facet Technologies, LLC	Same
510(k) Number	N/A	K221433
Product Code	FMK	QRK, QRL
Tip configuration	Bevel	Bevel
Needle Length	3.1±0.45 mm	Same
Needle Gauge	28G	Same
Body Color	Light blue	Same

Characteristic	Predicate Device	Subject Device
Needle Material	304 Stainless steel	Same
Body Material	Low density polyethylene (LDPE)	Same
Body/needle bond strength	$\geq$ 13.23 N	Same
Cap Twist-off torque	$\leq$ 4.9 N-cm	Same
Sterility	Sterilized by Gamma Radiation SAL = 10^{-6}	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 device continued to meet the specified requirements over the shelf life of the device. Physical testing included lancet body to needle bond strength, sterility cap twist-off torque, and compatibility with commercially available reusable lancet bases (lancing devices). Biocompatibility was evaluated through a battery of tests to meet ISO 10993-1 requirements.

Table 2: Summary of Nonclinical Tests Performed

Property/Characteristic	Test Method	Importance	Reference
Bond Strength of lancet blade (needle) to lancet body	Tensile strength tester	Ensure needle does not detach from lancet body during use	N/A
Sterility Cap Torque	Torque tester	Ensure that the cap can be easily removed by user when desired	N/A
Compatibility with lancet bases (lancing devices)	Simulated use	Ensure usability with commercially available lancet bases	N/A

Property/Characteristic	Test Method	Importance	Reference
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 28G Universal Lancet demonstrate a substantially equivalent safety and effectiveness profile to the predicate device and should perform as well as the predicate in the intended use conditions.