10/3/2022

Owen Mumford Ltd
% Patty Cronan
Quality Manager
Owen Mumford USA Inc.
1755 West Oak Commons Ct.
Marietta, Georgia 30062

Re: K221613
Trade/Device Name: Freestyle Lancing Device II, Autolet, Autolet Lite, Unilet Lancets
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: May 30, 2022
Received: June 3, 2022

Dear Patty Cronan:

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 and Part 809**);** 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,

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)*
K221613

Device Name
Freestyle Lancing Device II, Autolet, Autolet Lite, Unilet Lancets

Indications for Use *(Describe)*

Freestyle Lancing Device II: Use with compatible lancets for capillary blood sampling.

Autolet: Use with compatible lancets for capillary blood sampling.

Autolet Lite: Use with compatible lancets for capillary blood sampling.

Unilet Lancets: Use with compatible lancing device for capillary blood sampling.

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.

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SECTION 5.0

510(k) SUMMARY

1.Submitter

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Date Prepared: 16 AUG 2022

2.Device

Name of Device:	Freestyle Lancing Device II Autolet Autolet Lite Unilet Lancets
Common Name:	Home-use Lancing Device
Classification Name:	Multiple Use Blood Lancet for Single Patient Use Only
Product Code:	QRL
Subsequent Product Code:	QRK
FDA Classification:	Class II

3.Predicate Devices

Predicate Device Name: Accu-Chek Softclix Blood Lancing System, 510(k) number **K214022**.

4.Description of The Device

The purpose of this 510(k) Premarket Notification is to obtain FDA clearance for the following devices:

- Freestyle Lancing Device II
- Autolet
- Autolet Lite
- Unilet Lancets

The intended use for these devices remains the same as the predicate device.

The Autolet design is an Owen Mumford branded variant of the “Freestyle Lancing Device II”. The sole difference is the moulded branding on the outer of the rear body component, the component is functionally identical and made of the same material. Therefore, much of the information for the Freestyle Lancing Device II and Autolet devices is the same and they can be considered variants of the same device.

For brevity, in the sections within this submission pertaining to both the “Freestyle Lancing Device II” and “Autolet” devices, they will be referred to as the “FS & A Device”. When information provided is specific to one variant, its full name will be used. Additionally, any reference within the documentation referring to ‘Perceval’ can be considered as pertaining to the FS & A Device, as the original design work was performed under the project name Perceval.

The FS & A Device is a hand-held non-sterile, reusable lancing device intended for single patient capillary blood sampling in non-clinical environments. The ADC Freestyle Lancing Device II variant is sold for use with ADC ‘Freestyle’ single-use lancets; these are not included in this submission. The OM Autolet variant is sold for use with Unilet Lancets and as ‘universally compatible with most lancets’. The lancets are disposed of after each use and the device is maintained by using isopropyl alcohol or soap to wipe the outside of the device. The FS & A Device is for use only on a single patient.

The FS & A Device is intended to be used by patients with medical conditions who require frequent capillary blood sampling, such as diabetics. Frequency of use will depend greatly on the patients need for using the device, although typically diabetics may monitor their blood glucose levels several times per day. The primary site for lancing is the finger, although an ‘alternate site adapter’ is provided, so lancing can be performed on sites other than the fingers as necessary.

The Autolet Lite is a hand-held non-sterile, reusable lancing device intended for single patient capillary blood sampling in non-clinical environments. The device was designed for use as a system with Unilet Lancets (and as 'universally compatible with most lancets') which are included in this 510(k) The Unilet Lancets feature 3 lancet gauges, 3 with labelling "Unilet Lancets" and the same 3 lancet gauges labelled "Unilet ComforTouch Lancets". These lancets have different gauge sizes and styling but are functionally identical and for the purpose of this 510(k), all references to "Unilet Lancets" can be considered to apply to Unilet Lancets and Unilet ComforTouch Lancets.

5.Indications for Use

Freestyle Lancing Device II: Use with compatible lancets for capillary blood sampling.

Autolet: Use with compatible lancets for capillary blood sampling.

Autolet Lite: Use with compatible lancets for capillary blood sampling.

Unilet Lancets: Use with compatible lancing device for capillary blood sampling.

6. Technological Characteristics

The Autolet, Freestyle Lancing Device II device and the Autolet Lite and Unilet Lancets are substantially equivalent to the predicate device, the Accu-Chek Softclix Blood Lancing System, 510(k) number **K214022**.

A comparison of the intended uses and technological characteristics is summarized in the table 5.1 below.

Table 5.1 Comparison of the intended uses and technological characteristics between the predicate and submission devices

Device Characteristic	Accu-Chek Softclix Blood Lancing System	Submission Device – FS & A Device	Autolet Lite and Unilet Lancets
Device Description	The Accu-Chek Softclix Lancing Device uses compatible Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternative sites using the Accu-Chek Softclix Alternative Site Testing (AST) Cap.	The FS & A is a hand-held non-sterile, reusable lancing device intended for single patient capillary blood sampling in non-clinical environments. This is achieved by using the device with single-use blood lancets. The primary site for lancing is the finger, although an 'alternate site adapter' is provided, so lancing can be performed on sites other than the fingers as necessary.	The Autolet Lite is a hand-held non-sterile, reusable lancing device intended for single patient capillary blood sampling in non-clinical environments. This is achieved by using the device with single-use blood lancets, of which the Autolet Lite is sold for use with Unilet Lancets.
Intended Use	The Accu-Chek Softclix Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm.	Unchanged from the predicate device	Unchanged from the predicate device

Device Characteristic	Accu-Chek Softclix Blood Lancing System	Submission Device – FS & A Device	Autolet Lite and Unilet Lancets
Indications for Use	The Accu-Chek Softclix Blood Lancing System is intended for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the palm, the upper arm, and the forearm. The sterile, single-use lancets are to be used with the resuseable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. This system if for use only on a single patient in a home setting. This system is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.	Freestyle Lancing Device II: Use with compatible lancets for capillary blood sampling. Autolet: Use with compatible lancets for capillary blood sampling.	• Autolet Lite: Use with compatible lancets for capillary blood sampling. • Unilet Lancets: Use with compatible lancing device for capillary blood sampling.
Number of Uses	• Base (lancing device): multiple use • Lancet: single use	• Base (lancing device): multiple use • Lancet: single use	• Base (lancing device): multiple use • Lancet: single use
Depth Adjustment	11 levels by twisting cap	Levels 1-5, with half settings for a total of 9 different settings, set by twisting dial.	10 different settings, set by twisting cap
Depth of Penetration	Minimum depth of penetration: 0.8mm Maximum depth of penetration: 2.3mm	Minimum depth of penetration: 0.5mm Maximum depth of penetration: 2.5mm	Minimum depth of penetration: 0.60mm Maximum depth of penetration: 1.95mm

Device Characteristic	Accu-Chek Softclix Blood Lancing System	Submission Device – FS & A Device	Autolet Lite and Unilet Lancets
Load and firing	• Load by pressing priming button when lancet is inserted • Fire by pressing the release button	• Load by pulling back grey slider until it clicks (after lancet has been inserted) • Fire by pressing the lancing button	• Load by inserting the lancet into the lancet holder and pushing down until fully seated • Fire by pressing the release button
Mechanical Loading	Spring-driven	Spring-driven	Spring-driven
Lancet Sterility	Yes, gamma irradiation	Yes, gamma irradiation	Yes, Gamma irradiation
Lancet Dimensions	28G, 0.4mm wide, beveled cut with 3 facets. Needle length not known.	N/A – this column covers the devices only.	Unilet Lancets: 23G 0.64mm wide, 28G 0.36mm wide, 30G 0.31mm wide All lancets have the same needle length 3.2mm (+-0.3mm) Needle drawings can be found in section 11 – Device Description, of this submission.

7.Performance Data

Non-clinical performance data:

Design verification testing of the FS & A has been carried out to evaluate the performance of the devices against defined acceptance criteria.

The following table provides a summary of the relevant design verification testing.

Bench Testing:

The objective of the design verification testing conducted was to verify that the submission devices met the pre-determined specifications, to support the conclusion that they are fit for purpose and are considered safe and effective for the intended use.

Submission Device	Design Verification Testing	Results
FS & A Device	Yes – 20 Design Input IDs Tested and Verified	Passed all testing and verification
Autolet Lite	Yes – 12 Design Inputs Tested and Verified	Passed all testing and verification
Unilet Lancets	Yes – 12 Design Inputs Tested and Verified	Passed all testing and verification

Biocompatibility:

All patient contact materials of the FS & A Device were assessed against the requirements of ISO 10993-1:2009. All skin contact materials used in the device were tested for cytotoxicity in accordance with ISO 10993-5:2009. These results along with base material and master-batch data sheets, the proposed material application, the device assembly process and any examples of current usage were used by the Toxicologist (Medwise International Consultancy Limited, York UK) to assess the suitability of the materials for their intended use and provide a biocompatibility evaluation. All contact materials were found to be non-cytotoxic according to the test method stipulated in ISO 10993-5:2009: Each material scored 0; the lowest level achievable. Expert toxicological review for the materials concluded that “it is inconceivable that transient daily skin contact with the device would result in any incidence of irritation or sensitization” to users and therefore the requirements of ISO 10993 are met without the need for further animal testing.

Results of the testing and toxicological assessment demonstrate the materials of the FS & A Device are biocompatible and do not pose a biological risk to the user, therefore, safe for use.

Sterilization:

Unilet Lancets are the only device in this submission that is provided sterile.

Sterilization Method: Gamma radiation

Radiation dose range: 25-50 kGy

Sterility assurance level (SAL): 10^{-6}

Description of the method used to validate the sterilization cycle:

Sterilization validation (Dose mapping) was conducted in accordance with Section 9 of *ISO 11137: "Sterilization of Healthcare Products – Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices."*

The verification dose for the Unilet Lancets manufactured by Tianjin Huahong Technology Co., Ltd is 6.5kGy and the minimum exposure dose has been determined as 25kGy.

Shelf life

The FS & A Device is designed to last for 2 years as per the design verification for the device.

Unilet Lite is designed to last for no less than 3000 complete uses.

Unilet Lancets have a sterile shelf life of 5 years.

8.Conclusion

In summary, the differences between the FS & A Device, Autolet Lite and Unilet Lancets and the predicate have no impact on safety and effectiveness and the products are therefore substantially equivalent to the predicate device.