September 8, 2023

STAT Medical Devices
% Kevin Walls
Senior Consultant
FDA Compliance Group
33 Golden Eagle Lane
Littleton, Colorado 80127

Re: K230310
Trade/Device Name: STAT Medical Device Lancing System
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood Lancets
Regulatory Class: Class II
Product Code: QRL, QRK
Dated: August 8, 2023
Received: August 8, 2023

Dear Kevin Walls:

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); 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,

Jessica Carr -S

for Mark Trumbore, Ph.D., GWCPM
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K230310

Device Name

The STAT Medical Lancing Device Systems

Indications for Use *(Describe)*

Stat Medical Lancing Device Systems are intended for the hygienic collection of capillary blood for testing purposes from the side of a finger and from alternate site, such as the palm, the upper arm, and the forearm. The Stat Medical Lancing Device Systems are for single patient use 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.

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."

STAT Medical Lancing Device Systems 510(k) Summary

Date Prepared

September 5, 2023

Name and Address of Sponsor

STAT Medical Devices
2056 N.E. 153rd Street
North Miami Beach, FL 33162
Hemel Mariano (Quality Manager)
305-945-0011 Ext. 312
hmariano@statdevices.com

Establishment Registration Number: 1058955

Name and Address of Official Correspondent

FDA Compliance Group
33 Golden Eagle Lane
Littleton, Colorado 80127
Contact: Mr. Kevin Walls, MBA
Telephone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

Device Information

Trade Name: STAT Medical Lancing Device Systems

- ULTIMATE Lancing Device
- TRIO Lancing Device
- Comfort Thins Twist-Off Lancet (K222034)
- Comfort Thins Pull Off Lancet (K221383)

Common Name: Blood Lancets & Lancing Devices

Regulation Name: Blood Lancets

Regulation Number: 878.4850, Class II

Product Code: QRL, QRK

Device Description

The Stat Medical Lancing Device Systems consist of two types of lancing devices:

ULTIMATE Lancing Device

Single-person, multiple-use device

Made of ABS plastic and SUS304 stainless-steel springs.

8 depth-setting choices

TRIO Lancing Device

Single-person, multiple-use device

Made of ABS plastic and SUS304 stainless-steel springs.

5 depth-setting choices

Lancet Ejector

The Stat Medical Lancing Device Systems consist of two types of representative (generic) lancets:

COMFORT THIN Twist-Off Lancets

Sterile, single-person, single use device

Made of LDPE plastic with a SUS304 stainless-steel needle tip

LDPE injection-molded, plastic cover over the sterile tip

COMFORT THIN Pull-Off Lancets

Sterile, single-person, single use device

Made of ABS and PP plastic with a SUS304 stainless-steel needle tip

ABS and PP plastic cover over the sterile tip

ULTIMATE Lancing Device

Device Catalog Number: SM-QLU-L02

AST Cap Catalog Number: SM-QLU-A02

The intended use of the ULTIMATE Lancing Device is to function as a single-person reusable device that holds a lancet to puncture the skin for capillary blood sampling for blood glucose testing. It is not to be used for assisted blood draws by healthcare providers or at healthcare provision sites.

The ULTIMATE Lancing Device is made of ABS plastic and SUS304 stainless-steel springs.

The ULTIMATE has 8 depth-setting choices. The device requires that the lancing device end cap be removed, a single lancet be inserted into the lancet holder and then the lancing device end cap placed back onto the device. The user is able to set the desired depth penetration level by moving the depth selector. The lancing device is then cocked by pulling the back end of the device away from the lancet body. To fire the device the firing button is depressed. Once the lancet has been fired it moves forward to pierce the patients' test site with the lancet. After piercing the skin the lancet then travels back into the housing of the lancing device. The lancing device end cap is removed and then the lancet is removed. It is then disposed of into an appropriate container. The body and lancing device end cap are cleaned with soap and warm water and allowed to air dry after each use and disinfected per the IFU, as needed.

If the patient is testing from a site other than the finger an optional AST Cap may be put onto the device instead of the "standard" lancing device end cap.

The ULTIMATE Lancing Device has an Alternative Site Test (AST) Cap, which may be purchased separately. The AST cap allows the user to obtain a blood sample from parts of the body other

than the fingers. (The user must refer to their Glucose Meter Instructions for Use for the meter/test strips they are using for identification of alternative test sites.). The lancing device end cap is cleaned after every use and when visibly dirty and before disinfection. Disinfection is performed between each use. Cleaning involves use of a damp cloth and mild detergent to wipe the outside of the lancing device end cap, followed by wiping dry. The device is disinfected via wiping down with a cloth dampened in a bleach solution (bleach wipes) and allowed to air dry.

TRIO Lancing Device

Device Catalog Number: SM-TLD-L02

AST Cap Catalog Number: SM-TLD-A02

The intended use of the TRIO Lancing Device is to function as a single-person reusable device that holds a lancet to puncture the skin for capillary blood sampling for blood glucose testing. It is not to be used for assisted blood draws by healthcare providers or at healthcare provision sites

The TRIO Lancing Device is made of ABS plastic and SUS304 stainless-steel springs.

The TRIO has 5 depth-setting choices. The device requires that the lancing device end cap be removed, a single lancet be inserted into the lancet holder and then the lancing device end cap placed back onto the device. The user is able to set the desired depth penetration level by moving the depth selector. The lancing device is then cocked by pulling the back end of the device away from the lancet body. To fire the device the firing button is depressed. Once the lancet has been fired it moves forward to pierce the patients' test site with the lancet. After piercing the skin, the lancet then travels back into the housing of the lancing device. The lancing device end cap is removed and then the lancet is removed using the lancet ejector. It is then disposed of into an appropriate sharps container. The lancing device end cap and device are cleaned after each use and when they are visibly dirty or show signs of blood and before disinfection but are cleaned at least once per week. Disinfection is performed between each use. Cleaning involves use of a damp cloth and mild detergent to wipe the outside of the device and lancing device end cap, followed by wiping dry. Disinfection involves use of a wipe with a bleach solution or bleach wipes. The lancing device end cap is disinfected and allowed to air dry.

If the patient is testing from a site other than the finger an optional AST Cap may be put onto the device instead of the "standard" lancing device end cap.

The TRIO Lancing Device has an Alternative Site Test (AST) Cap, which may be purchased separately. The AST cap allows the user to obtain a blood sample from parts of the body other than the fingers. (The user must refer to their Glucose Meter Instructions for Use for the meter/test strips they are using and healthcare professional for identification of alternative test sites.). The AST cap is cleaned and disinfected in the same manner as the lancing device and standard cap.

The Alternate Site Testing (AST) Cap is a single-person multi-use optional plastic accessory for the lancing device. It may be used in place of the original lancing device end cap when a patient is taking a blood sample from a site on the body other than the finger. Proper use of the device requires that the user first verify with their physician and the Instructions for Use of the blood glucose test strips or meter they are using to determine if AST testing is appropriate.

Comfort Thins Twist-Off Lancets

The Comfort Thins Twist-Off Lancet has 2 parts, the lancet cannula that includes the lancet point (solid stainless-steel needle), and the lancet body that includes the protective cover (or tab) of the device which are molded together and the tab is twisted off for use by the end user.

The Comfort Thins Twist-Off Lancet body and cover are made of LDPE plastic. The needle is

made from SUS304 stainless steel. The device is provided sterile and is for single-use only.

Comfort Thins Twist-Off Lancets are offered in a variety of needle gauge sizes. The table below provides a list of the devices available from SMD.

Product Name	Catalog Number
Comfort Thins Twist-Off 28g	SCT-100 (28G)
Comfort Thins Twist-Off 29g	STX-100 (29G)
Comfort Thins Twist-Off 30g	STM-100 (30G)
Comfort Thins Twist-Off 33g	STU-100 (33G)

The Comfort Thins Twist-Off Lancets do not have any accessories and do not require interaction with other devices in order to function. However, it is recommended that the lancet be loaded into a standard lancing device for use.

Comfort Thins Lancets – Pull Off

The Comfort Thins Lancet has 2 parts, the lancet cannula that includes the lancet point (solid stainless-steel needle), and the lancet body that includes the protective cover (hollow cap) of the device.

The Comfort Thins Lancet's body and cover are made of ABS and PP plastics. The needle is made from stainless steel SUS304. The device is provided sterile and is for single-use only.

Comfort Thins Pull Off Lancets are offered in a variety of needle gauge sizes. The table below provides a list of the devices available from SMD.

Product Name	Catalog Number
Comfort Thins MACRO Lancets	SCA-100 (21G)
Comfort Thins Lancets	SCR-100 (28G)
Comfort Thins XTRA Lancets	SCX-100 (29G)
Comfort Thins MICRO Lancets	SCM-100 (30G)
Comfort Thins ULTRA Lancets	SCU-100 (33G)

The Comfort Thins Pull Off Lancets do not have any accessories and do not require interaction with other devices in order to function. However, it is recommended that the lancet be loaded into a standard lancing device for use.

Indications for Use

Stat Medical Lancing Device Systems are intended for the hygienic collection of capillary blood for testing purposes from the side of a finger and from alternate site, such as the palm, the upper arm, and the forearm. The Stat Medical Lancing Device Systems are for single patient use in a home setting.

Legally Marketed Predicate Device

Predicate #: K214022

Predicate Trade Name: Accu-Chek Softclix Blood Lancing System

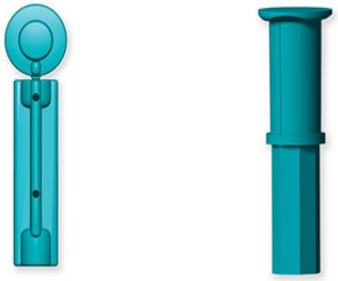
Manufacturer: Roche Diabetes Care, Inc.

Product Code: QRL, QRK

Similarities and Differences between Candidate Device and Predicate Device:

	Candidate Device – Stat Lancing Device System	Predicate Device – Accu-Chek Softclix Blood Lancing System K214022	Reference Device - TRUEdraw Lancing Device, Mini Lancing Device K221072
Manu-facturer	STAT Medical Devices	Roche Diabetes Care, Inc.	Trividia Health
Device Description	Stat Medical Lancing Device Systems use Stat Medical and representative lancets to obtain a drop of blood from a fingertip or alternate sites using the Stat Medical Alternate Site Testing (AST) Cap.	Accu-Chek Softclix Blood Lancing Device uses Accu-Chek Softclix Lancets to obtain a drop of blood from a fingertip or alternate sites using the Accu-Chek Softclix Alternate Site Testing (AST) Cap.	The TRUEdraw Lancing Device/ Mini Lancing Device is a reusable blood lancet holder intended to be used in conjunction with a sterile, single-use blood lancet for obtaining a capillary blood sample for testing purposes from the fingertip and from alternative sites, such as the forearm.
Intended Use	The Stat Medical Lancing Device Systems are intended for the hygienic collection of capillary blood for testing purposes from the side of a finger and from alternate site, such as the palm, the upper arm, and the forearm. The Stat Medical Lancing Device Systems are for single patient use in a home setting.	Accu-Chek Softclix Blood Lancing Device System is intended for the hygienic collection of capillary blood for testing purposed from the side of a finger and from alternate site, such as the palm, the upper arm, and the forearm.	TRUEdraw Lancing Device/ Mini Lancing Device is intended for multiple use by a single patient.
Indications for Use	Stat Medical Lancing Device Systems are intended for the hygienic collection of capillary blood for testing purposes from the side of a finger and from alternate site, such as the palm, the upper arm, and the forearm. The Stat Medical Lancing Device Systems are for single patient use in a home setting.	The Accu-Chek Softclix sterile, single-use lancets are to be used with the reusable lancing device that is to be cleaned and disinfected between each use, and then the lancets are to be disposed of. The system is 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	The TRUEdraw Lancing Device is for use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the forearm. The Mini Lancing Device is for use with a disposable sterile lancet for the hygienic collection of capillary blood for testing purposes from the side of a fingertip and from alternative sites, such as the forearm.

			The TRUEdraw Lancing Device/ Mini Lancing Device is for use only on a single patient in a home setting. The TRUEdraw Lancing Device/ Mini Lancing Device is not suitable for use by healthcare professionals with multiple patients in a healthcare setting.
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

Device Images	Lancing Device & AST Cap:  TRIO Device & AST Cap:  Twist-Off Lancet Pull-Off Lancet 	Lancing Device & AST Cap:   Lancet: 	

Lancet Sterility	Yes, gamma irradiation	Yes, gamma irradiation	
Needle	0.33mm (28G); beveled cut with 3 facets (both lancets)	0.4mm (28G); beveled cut with 3 facets	
Depth Adjustment	TRIO – 5 depth settings ULTIMATE – 8 depth settings By sliding lever or rotating dial	11 levels by twisting cap	5 levels by twisting nozzle/end cap (finer adjustments can be made by setting the indicator arrow between the numbers)
Range of Depth (mm) *30 samples*	**Length of Lancet (MM)** Minimum: 26.23 Max: 26.63 **Ultimate Lancing Device** Depth 1 Minimum: 0.095 Max: 0.665 Depth 2 Minimum: 0.285 Max: 0.855 Depth 3 Minimum: 0.38 Max: 0.855 Depth 4 Minimum: 0.475 Max: 0.855 Depth 5 Minimum: 0.475 Max: 0.855 Depth 6 Minimum: 0.57 Max: 0.855 Depth 7 Minimum: 0.57 Max: 0.95 Depth 8 Minimum: 0.665 Max: 0.95 **Length of Lancet (MM)** Minimum: 26.23 Max: 26.63 **TRIO Lancing Device**	**Length of Lancet (MM)** Minimum: 25.22 Max: 25.31 Level 1 Minimum: 0 Max: 0.095 Level 2 Minimum: 0.095 Max: 0.38 Level 3 Minimum: 0.19 Max: 0.475 Level 4 Minimum: 0.38 Max: 0.665 Level 5 Minimum: 0.475 Max: 0.665 Level 6 Minimum: 0.475 Max: 0.76 Level 7 Minimum: 0.57 Max: 0.855 Level 8 Minimum: 0.57 Max: 0.855 Level 9 Minimum: 0.665 Max: 0.855 Level 10 Minimum: 0.665 Max: 0.95 Level 11 Minimum: 0.76 Max: 0.95	N/A

	Depth 1 Minimum: 0.095 Max: 0.38 Depth 2 Minimum: 0.38 Max: 0.76 Depth 3 Minimum: 0.475 Max: 0.855 Depth 4 Minimum: 0.475 Max: 0.855 Depth 5 Minimum: 0.57 Max: 0.95		
Range of Depth + AST Cap (mm) *30 samples*	**Ultimate Lancing Device + AST Cap** Depth 1 Minimum: 0 Max: 0 Depth 2 Minimum: 0 Max: 0.095 Depth 3 Minimum: 0 Max: 0.095 Depth 4 Minimum: 0 Max: 0.19 Depth 5 Minimum: 0 Max: 0.38 Depth 6 Minimum: 0.19 Max: 0.475 Depth 7 Minimum: 0.38 Max: 0.57 Depth 8 Minimum: 0.38 Max: 0.665 **TRIO Lancing Device + AST Cap** Depth 1 Minimum: 0 Max: 0 Depth 2 Minimum: 0 Max: 0 Depth 3 Minimum: 0 Max: 0.38 Depth 4 Minimum: 0.19 Max: 0.475 Depth 5 Minimum: 0.285 Max: 0.57	**Length of Lancet (MM)** Minimum: 25.22 Max: 25.31 Level 1 Minimum: 0 Max: 0 Level 2 Minimum: 0 Max: 0 Level 3 Minimum: 0 Max: 0 Level 4 Minimum: 0 Max: 0 Level 5 Minimum: 0 Max: 0 Level 6 Minimum: 0 Max: 0 Level 7 Minimum: 0 Max: 0 Level 8 Minimum: 0 Max: 0 Level 9 Minimum: 0 Max: 0 Level 10 Minimum: 0 Max: 0.19 Level 11 Minimum: 0.095 Max: 0.38	N/A

Mechanical Loading	Spring-driven	Spring-driven	Spring-driven
Load and Firing	Load by advancing lancet into holding section and pushing down, Fire by pressing release button	Load by pressing priming button when lancet is inserted, Fire by pressing release button	Load lancet by pulling back on the lance body when the lancet is inserted. Fire by pressing the • trigger button.
Anatomical Sites	Fingertip Ball of hand (palm) Upper arm Lower arm	Fingertip Ball of hand (palm) Upper arm Lower arm	Fingertip Forearm
Sharps Injury Prevention	Lancets are covered by a sterile barrier cap until twisted or pulled off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into the housing. An ejector sleeve can then be advanced forward for contactless disposal of the lancet.	Lancets are covered by a sterile barrier cap until twisted off before use. Until firing, the lancet is contained within the lancing device housing. Immediately after firing, the lancet is automatically retracted back into the housing. An ejector sleeve can then be pulled forward for contactless disposal of the lancet.	
Ejector sleeve	Ultimate Lancing Device: No Trio Lancing Device: Yes	Yes	No

Indication for Use Comparison

The indications for use of the candidate device system are the same as the predicate with the exception that the predicate device has a dedicated lancet and the candidate lancing device can be used with “standard” lancets.

Technological Comparison

The candidate and predicate devices share the same characteristics including their design, mechanical mechanism, principle of operation, energy source and usage, features, form, fit and function.

Non-clinical Testing Summary and Conclusions

Biocompatibility Testing

The medical device in its final finished form is identical to the EasyTouch Lancing Device (510(k) K222617) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Performance Testing

The following tests were performed: Penetration depth testing, cock force testing, drop testing, insertion force testing, removal force testing, and

migration distance testing.

The device complies with the following standards:

ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 10993-11 Third edition 2017-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-12 Fifth edition 2021-01	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization

Clinical Testing

Clinical testing is not applicable; risk analysis confirmed that all identified risks were addressed and mitigated appropriately. All residual risks after mitigation were acceptable and communicated in the instructions for use (IFU) as warnings. There were no special performance or safety concerns identified.

Conclusion

The results of nonclinical testing demonstrate that the subject device is the same or similar to the predicate devices K214022 and K221072 and should perform as intended in the specified use conditions as well as the predicate device per required standards.