August 12, 2022

Tasso, Inc.
Trish Kan Brown
Director of Regulatory Affairs
1631 15th Ave W, Suite 105
Seattle, Washington 98119

Re: K221131
Trade/Device Name: Tasso+
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: FMK
Dated: July 11, 2022
Received: July 15, 2022

Dear Trish Kan Brown:

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 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)*
K221131

Device Name
Tasso+

Indications for Use *(Describe)*
The Tasso+ is a single-use blood lancing device intended for obtaining microliter capillary whole blood samples.

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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510(k) Summary

1. Submitter

Tasso, Inc.
1631 15th Ave W, Suite 105
Seattle, WA 98119
USA

2. Contact Person

Trish Kan Brown
Director of Regulatory Affairs
Telephone: (206) 822-4186 x1063
E-mail: tkanbrown@tassoinc.com

3. Date Prepared

August 11, 2022

4. Device / Marketing Trade Name

Tasso+

5. Common / Usual Name

Blood lancet, single-use

6. Classification

Regulatory Device Class: II
Classification Panel: General & Plastic Surgery

Classification Name	21 CFR Number	Product Code
Blood Lancets	878.4850	FMK

7. Predicate Device

Tianjin Huahong Technology Safety Lancet (K220370); Product Code: FMK

8. Device Description

The Tasso+ device is a sterile, disposable blood lancet. After attachment of a compatible third-party collection tube, the backing is removed from the medical adhesive that is located on the skin side of the device. The device is adhered, in position, to the skin by this adhesive backing.

The device is actuated by pressing the button, causing an energized spring to release and swing the lancet assembly containing a single stainless-steel lancet in an arching motion to create an incision. The lancet contacts the patient momentarily, less than one second, to create a single incision. The mechanism automatically positions the lancet in an inactive position after it has made the incision to prevent sharps injury or re-actuation.

In addition to deploying the lancet, the push of the button generates a slight vacuum to facilitate blood flow under gravity into the blood collection tube. The blood flows from the

incision via an open channel in the base and into the compatible tube. The blood flow is one-way, from the skin to the tube, preventing blood re-exposure.

The user is instructed to stop blood collection after a maximum of five minutes of draw time or when the blood reaches the maximum volume fill indicator on the attached tube. The device is then peeled off the skin, and the compatible third-party tube is removed and capped for transport.

9. Intended Use / Indications for Use

The Tasso+ is a single-use blood lancing device intended for obtaining microliter capillary whole blood samples.

10. Basis for Substantial Equivalence

Tasso+ is substantially equivalent to its predicate device with regards to intended use, technological characteristics, and safety and effectiveness. A comparison table is provided below.

Characteristic	Predicate: Safety Lancet Tianjin Huahong Technology Co., Ltd. (K220370)	Application Device: Tasso+ Tasso, Inc. (this 510(k) submission)
Indications for Use	The safety lancet is intended for capillary blood sampling.	The Tasso+ is a single-use blood lancing device intended for obtaining microliter capillary whole blood samples.
FDA Product Code	FMK	FMK
Prescription or Over-The-Counter	Over-The-Counter	Prescription
Sample Type Collected	Capillary whole blood	Capillary whole blood
Lancing Device	Single lancet	Single lancet
Blood Flow Facilitation	Palpation of incision	Slight vacuum maintained over the incision
Puncture Site Creation Mechanism	Spring loaded linear incision that actuates when device is pressed against skin	Torsion spring loaded arcing/swinging incision that actuates when button is pressed
Number of Uses	Single use	Single use
Non-Reusability Feature	Yes	Yes; self-locking mechanism after use
Sharps Injury Prevention	Cap pulled off before use to prevent accidental actuation. Lancet retracts into body of device after activation.	Button cover removed before use to prevent accidental actuation. Lancet retracts into body of device after activation.
Patient Contact Materials	Lancet: stainless steel Body and cap: ABS, PS	Lancet: stainless steel Body/housing: PC-ABS
Sterile Device	Yes	Yes
Collection Accessories	Compatible third-party tube	Compatible third-party tube

11. Non-Clinical Performance Data

Tasso+ has been designed and evaluated to comply with the following applicable FDA-

recognized consensus standards. All verification and validation testing for Tasso+ confirms that product specifications are met and are equivalent in design and technological and performance characteristics as the predicate device.

- ANSI AAMI ISO 11137-1:2006/(R)2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2019)]
- ANSI AAMI ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ANSI AAMI ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
- ASTM D7386-16 Standard Practice for Performance Testing of Packages for Single Delivery Systems
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F2096-11 (Reapproved 2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less
- ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ANSI AAMI IEC 62366-1:2015+AMD1:2020(Consolidated Text) Medical devices - Part 1: Application of usability engineering to medical devices, including Amendment 1

Tasso+ is also in compliance with the special controls described in 21 CFR 878.4850(a)(2).

12. Clinical Performance Data

An assessment of clinical performance data for Tasso+ successfully demonstrated its ability to collect blood samples from the upper arm of human subjects according to the device labeling. Subjects self-collected their blood samples following the Tasso+ instructions for use. The devices demonstrated that the minimum acceptable volume collected was within the lower limit of the 90% confidence interval. The devices had a total success rate of 94.2% and demonstrated that they performed as intended with a compatible tube.

13. Conclusion

The technological differences do not pose any new questions of safety or efficacy. Bench and clinical performance data demonstrate that the subject device can perform as intended when used according to the labeling. Therefore, the Tasso+ device is substantially equivalent to the predicate device in terms of safety and effectiveness for the requested indications for use.