March 2, 2023

Accriva Diagnostics, Inc.
Wenni Haley
Senior Principal Specialist, Regulatory Affairs
6260 Sequence Drive
San Diego, California 92121

Re: K223352
Trade/Device Name: Tenderfoot
Regulation Number: 21 CFR 878.4850
Regulation Name: Blood lancets
Regulatory Class: Class II
Product Code: FMK
Dated: November 1, 2022
Received: November 2, 2022

Dear Wenni Haley:

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)*
K223352

Device Name
Tenderfoot Newborn, Tenderfoot Micro-Preemie, Tenderfoot Preemie, Tenderfoot Toddler

Indications for Use *(Describe)*
Tenderfoot is a sterile incision device intended to initiate capillary blood flow via a heel stick with infants and toddlers.

For medical device use. For healthcare professional use, prescription only.

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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510(k) Summary

I. SUBMITTER

Applicant:	Accriva Diagnostics, Inc. 6260 Sequence Drive San Diego, CA 92121 USA Establishment Registration Number: 3002721930
Application Correspondent:	Wenni Haley Senior Principal Specialist, Regulatory Affairs Phone: 858-263-2322 Email: whaley@werfen.com
Date Prepared:	March 1, 2023

II. DEVICE

Trade Name:	Tenderfoot
Common Name:	Heel Incision Device
Classification Name:	Single use only blood lancet with an integral sharps injury prevention feature
Regulation Number:	21 CFR 878.4850
Regulatory Class:	Class II
Product Code:	FMK
Review Panel:	General and Plastic Surgery (79)

III. PREDICATE DEVICE

Primary Predicate:	Tenderfoot (K883968), Product Code: FMK
Additional Predicate:	Tenderfoot (K911997), Product Code: FMK

IV. DEVICE DESCRIPTION

Tenderfoot is an automated skin incision device used to collect capillary blood from infants and toddlers by heel stick. The device produces an arc-like incision at a controlled depth to provide blood flow for obtaining a blood sample. The incision is made by a surgical blade that is completely enclosed in a plastic housing and deployed by pressing a trigger. Following deployment, the blade permanently retracts within the housing, rendering the device inoperable for further use.

Tenderfoot is provided as a sterile, single-use disposable device intended for use by healthcare professionals only. Sterilization is achieved by gamma irradiation.

Tenderfoot is offered in four models covering a range of incision depths sized for different infant populations: Micro-Preemie, Preemie, Newborn, and Toddler (see table below).

Tenderfoot Model	Incision Depth	Incision Length	Color
Micro-Preemie	0.65 mm	1.40 mm	Blue
Preemie	0.85 mm	1.75 mm	White
Newborn	1.00 mm	2.50 mm	Blue/Pink
Toddler	2.00 mm	3.00 mm	Pink

Tenderfoot is not marketed with accessories or as part of a system.

V. INDICATIONS FOR USE

Tenderfoot is a sterile incision device intended to initiate capillary blood flow via a heel stick with infants and toddlers.

For medical device use. For healthcare professional use, prescription only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A detailed comparison between the predicate, the currently marketed Tenderfoot device (K883968 and K911997), and the subject Tenderfoot device is provided in the table below to demonstrate substantial equivalence.

Characteristic	**Predicate** **Tenderfoot (K883968, K911997)**	**Subject Device** **Tenderfoot (this submission)**
Similarities		
Indications for Use / Intended Use	Tenderfoot is a sterile incision device intended to initiate capillary blood flow via a heel stick with infants and toddlers for use in diagnostic testing. For medical device use. For healthcare professional use, prescription only.	Tenderfoot is a sterile incision device intended to initiate capillary blood flow via a heel stick with infants and toddlers. For medical device use. For healthcare professional use, prescription only.

Characteristic	**Predicate** **Tenderfoot (K883968, K911997)**	**Subject Device** **Tenderfoot (this submission)**
Principle of Operation	Incision made by a spring-loaded, cam-driven surgical steel blade moving in a single sweeping motion, actuated by pressing a trigger.	Incision made by a spring-loaded, cam-driven surgical steel blade moving in a single sweeping motion, actuated by pressing a trigger.
Sharps Injury Prevention Features	1. Blade permanently retracts following deployment. 2. Housing completely encloses the blade and prevents finger access. 3. Detachable trigger guard prevents accidental/premature actuation. 4. Indicator arrow indicates exit path of the blade. 5. Device can be activated with a single hand. 6. Trigger remains visibly depressed to show device has already been activated.	1. Blade permanently retracts following deployment. 2. Housing completely encloses the blade and prevents finger access. 3. Detachable trigger guard prevents accidental/premature actuation. 4. Indicator arrow indicates exit path of the blade. 5. Device can be activated with a single hand. 6. Trigger remains visibly depressed to show device has already been activated.
Incision Profiles (Depth/Length)	Micro-Preemie: 0.65 mm / 1.40 mm Preemie: 0.85 mm / 1.75 mm Newborn: 1.00 mm / 2.50 mm Toddler: 2.00 mm / 3.00 mm	Micro-Preemie: 0.65 mm / 1.40 mm Preemie: 0.85 mm / 1.75 mm Newborn: 1.00 mm / 2.50 mm Toddler: 2.00 mm / 3.00 mm
Housing Colors	Micro-Preemie: Blue Preemie: White Newborn: Blue/Pink Toddler: Pink	Micro-Preemie: Blue Preemie: White Newborn: Blue/Pink Toddler: Pink
Housing Dimensions	Width: 1.3 in Height: 1.2 in (excluding trigger guard) Depth: 0.5 in	Width: 1.3 in Height: 1.2 in (excluding trigger guard) Depth: 0.5 in
Incision Blade Design	Double-honed surgical blade	Double-honed surgical blade
Materials	<u>Patient-Contacting</u> 1. Housing: Polystyrene 2. Surgical Blade: Stainless steel <u>Non-Patient Contacting</u> 3. Cam follower: Polycarbonate/acrylic alloy 4. Torsion Spring: Stainless steel 5. Trigger: Polystyrene 6. Trigger Guard: Polystyrene	<u>Patient-Contacting</u> 1. Housing: Polystyrene 2. Surgical Blade: Stainless steel <u>Non-Patient Contacting</u> 3. Cam follower: Polycarbonate/acrylic alloy 4. Torsion Spring: Stainless steel 5. Trigger: Polystyrene 6. Trigger Guard: Polystyrene

Characteristic	Predicate Tenderfoot (K883968, K911997)	Subject Device Tenderfoot (this submission)
Packaging System	Primary (sterile barrier) 1. Blister Pack Tray: Polyethylene terephthalate (PETG) 2. Lid: Tyvek Secondary 3. Box: Clay-coated news back	Primary (sterile barrier) 1. Blister Pack Tray: Polyethylene terephthalate (PETG) 2. Lid: Tyvek Secondary 3. Box: Clay-coated news back
Packaging (Boxed) Configurations	Micro-Preemie: 50 pack Preemie: 50 pack, 200 pack, 1000 pack Newborn: 50 pack, 200 pack, 1000 pack Toddler: 50 pack	Micro-Preemie: 50 pack Preemie: 50 pack, 200 pack, 1000 pack Newborn: 50 pack, 200 pack, 1000 pack Toddler: 50 pack
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1
Sterilization	Gamma irradiation Sterility Assurance Level (SAL) of 10^{-6}	Gamma irradiation Sterility Assurance Level (SAL) of 10^{-6}
Number of Uses	Single use only	Single use only
Shelf Life	4 years	4 years
Differences		
Labeling	Does not contain all labeling information required by the special controls under 21 CFR 878.4850(a)(2).	Contains all labeling information required by the special controls under 21 CFR 878.4850(a)(2).

VII. PERFORMANCE DATA

The following nonclinical performance data were provided in support of the substantial equivalence determination and compliance with the special controls described in 21 CFR 878.4850(a)(2).

Performance Testing – Bench

Nonclinical bench testing was performed for cut depth, cut length, trigger activation, and blade retraction before and after stress conditions, such as simulated distribution and aging. The testing met all acceptance criteria.

Biocompatibility Testing

Biocompatibility evaluation for Tenderfoot was conducted in accordance with the FDA Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'" and ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Testing was successfully completed for the following endpoints:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Material-mediated pyrogen testing
- Hemocompatibility

Sterilization and Shelf Life

Sterilization by gamma irradiation was validated per ISO 11137-1 and demonstrated a Sterility Assurance Level (SAL) of 10^{-6}.

Sterile barrier packaging testing was conducted for packaging performance and stability in accordance with ISO 11607-1. Package integrity tests included:

- Visual inspection of seal width
- Seal strength (ASTM F88/F88M)
- Gross leaks (ASTM F2096)
- Microbial barrier (ASTM F1608)

A packaging shelf life of 4 years was established through accelerated aging per ASTM F1980.

VIII. CONCLUSIONS

Based on the information provided in this submission, Accriva Diagnostics concludes that the subject device, Tenderfoot, is substantially equivalent to the predicate device (K883968 and K911997). The labeling differences between the subject and predicate do not raise new concerns of safety and effectiveness.