November 17, 2017

Sandstone Diagnostics, Inc.
Ulrich Schaff
Chief Technology Officer
6111 Southfront Road, Suite J
Livermore, California 94551

Re: K172514
Trade/Device Name: Trak Plus Male Fertility Testing System
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: POV
Dated: August 18, 2017
Received: August 21, 2017

Dear Ulrich Schaff:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K172514

Device Name
Trak® Male Fertility Testing System

Indications for Use *(Describe)*
The Trak® Male Fertility Testing System is intended for semi-quantitative assessment of sperm concentration at 15 million sperm per milliliter (M/mL) or below, between 15 and 55 M/mL, and above 55 M/mL. It also provides a qualitative assessment of semen volume.

Sperm concentration and semen volume are only two factors that could impact a man's fertility status and time to pregnancy. For complete assessment of male reproductive health, the user should consult a physician. For in vitro, over the counter home use.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K172514.

807.92 (a)(1): Name: Sandstone Diagnostics, Inc.
Address: 6111 Southfront Road, Suite J
Livermore, CA 94551

Phone: 925-315-7246
FAX: 925-215-2269
Contact: Ulrich Schaff, PhD

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:
Trak® Male Fertility Testing System

Common Name: Semen Analysis Test

Classification: 21 CFR § 864.5220

807.92 (a)(3): Identification of the legally marketed predicate devices
Trak® Male Fertility Testing System, Sandstone Diagnostics, Inc., Livermore, CA, K153683

807.92 (a)(4): Device Description
The revised Trak® Male Fertility Testing System (Trak) includes a small instrument (the Engine), disposable units in which liquefied semen sample is introduced and the result is interpreted (the Props), and consumables, including Volume Cups and sample droppers.

The Volume Cups are used collect, liquefy, and assess the volume of the semen sample. Markings on the Volume Cup allow the interpretation of volume at/below or above the 1.5 mL threshold. The Trak Engine and Props allow for the semi-quantitative assessments of total sperm concentration: below 15 million/mL, between 15 and 55 million/mL, and above 55 million/mL.

Trak uses the principle of density gradient separation to isolate sperm cells from human semen to provide an estimation of sperm concentration. The Trak Engine spins a test Prop to compact sperm cells within an introduced semen sample into a visible column (or "pellet"). The Prop gives a defined shape to the column, the height of which corresponds to the concentration of sperm cells in the sample. Since semen may also contain cell debris, immature sperm cells, and other contaminant particulates that could contribute to the apparent size of a pellet, it is necessary to filter out the contaminants. Trak achieves this filtering by removing contaminants from view based on density across a predefined liquid density medium.

During operation, approximately 0.17 mL of semen is metered by centrifugal action from the sample inlet into the metering chamber of the Prop. During rotation, the semen floats on "top" of the pre-loaded density medium. Sperm cells pass through the medium due to their high density while contaminants remain floating on the medium. When the spin sequence is complete, the sperm cells form a visible column that is displayed to the user for interpretation. Contaminants that are less dense than the liquid density medium are suspended "above" the medium, substantially separated from the sperm cells and are generally too diffuse to visualize.

807.92 (a)(5): Intended Use

The Trak® Male Fertility Testing System is intended for semi-quantitative assessment of sperm concentration at 15 million sperm per milliliter (M/mL) or below, between 15 and 55 M/mL, and above 55 M/mL. It also provides a qualitative assessment of semen volume.

Sperm concentration and semen volume are only two factors that could impact a man's fertility status and time to pregnancy. For complete assessment of male reproductive health, the user should consult a physician. For *in vitro*, over the counter home use.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

The following chart describes similarities and differences between the revised Trak system and the predicate.

Comparison	**Subject Device** **Trak® Male Fertility Testing System** **(**revised)	**Predicate Device** **Trak® Male Fertility Testing System** **(K153683)**
Intended Use	The Trak® Male Fertility Testing System is intended for semi-quantitative assessment of sperm concentration at 15 million sperm per milliliter (M/mL) or below, between 15 and 55 M/mL, and above 55 M/mL. It also provides a qualitative assessment of semen volume. Sperm concentration and semen volume are only two factors that could impact a man's fertility status and time to pregnancy. For complete assessment of male reproductive health, the user should consult a physician. For in vitro, over the counter home use.	The Trak® Male Fertility Testing System is intended for semi-quantitative assessment of sperm concentration at 15 million sperm per milliliter (M/mL) or below, between 15 and 55 M/mL, and above 55 M/mL. Sperm concentration is only one factor that could impact a man's fertility status and time to pregnancy. For complete assessment of male reproductive health, the user should consult a physician. For *in vitro*, over the counter home use.
Class	Class II	Same
Regulation Number	21 CFR 864.5220	Same
Product Code	POV	Same
Branch	Hematology (81)	Same

Comparison	Subject Device Trak® Male Fertility Testing System (revised)	Predicate Device Trak® Male Fertility Testing System (K153683)
Class	Class II	Same
Test Type	Semi-Quantitative and Qualitative	Semi-Quantitative
Test Locale	Home use	Same
Sample Type	Human semen	Same
Test Reporting	Visual readout of cell column height and Visual readout of fluid height	Visual readout of cell column height
Test Principle	Centrifuged packed cell volume and graduated chamber fluid volume	Centrifuged packed cell volume
Concentration Primary Cut-off	15 M/mL (lower reference limit, WHO semen analysis guidelines 5th edition, 2010)	Same
Concentration Secondary Cut-off	55 M/mL (indication of reduced time to pregnancy based on Slama et al 2002 study)	Same
Volume Cut-off	1.5 mL (lower reference limit, WHO semen analysis guidelines 5th edition, 2010)	None
Test Control Method	External Quality Control test solution	Same

807.92 (b)(1): Brief Description of Nonclinical Data

Precision of Volume Cup

The objective of this study was to assess the precision of the Volume Cup. Three lots of Volume Cups were qualitatively evaluated by three operators over five days on 5 artificial semen samples with different volumes and were compared with the reference volume. Each combination of day and operator/lot were tested in 5 replicates to obtain 75 total replicates per semen volume.

Summary results

The following includes grand averages for each condition, sum for each category and percent correct calls with respect to the reference method.

ID #	Reference Volume (mL)	# Results ≤ 1.5 mL	# Results > 1.5 mL	% Correct	Quant Volume result grand average ± SD (mL)
1	1.2 mL	75	0	100	1.32 ± 0.12
2	1.3 mL	74	1	98.7	1.43 ± 0.09
3	1.5 mL	17	58	n/a*	1.61 ± 0.10
4	1.7 mL	1	74	98.7	1.86 ± 0.16
5	1.8 mL	0	75	100	1.93 ± 0.10

* no performance goal at the threshold; data tabulated for information, only

The following includes SD (mL) and %CV between Day, between Operator/Lot, and total for each concentration.

ID #	N	Mean	Residual		Between Day		Between Operator‡		Operator* Day†		Total SD and %CV	
			SD	CV	SD	CV	SD	CV	SD	CV	SD	CV
1	75	1.32	0.08	6.1%	0.07	5.0%	0	0.0%	0.06	4.8%	0.12	9.2%
2	75	1.43	0.06	4.0%	0.02	1.6%	0.02	1.3%	0.07	4.7%	0.09	6.5%
3	75	1.61	0.09	5.5%	0.00	0.0%	0.00	0.0%	0.05	2.8%	0.10	6.2%
4	75	1.86	0.09	5.0%	0.03	1.4%	0.00	0.3%	0.00	0.0%	0.10	5.2%
5	75	1.93	0.10	5.1%	0.02	1.2%	0.01	0.6%	0.00	0.0%	0.10	5.3%

‡Operator factor is convolved with Lot; each operator used a unique lot.
†This is an interaction effect, it was found to be significant for some volumes tested.

The Volume Cup meets expected concordance for precision within operators/lots, days, and runs.

Functional Equivalence to Previous Cup
A series of studies were performed to prove that the Volume Cup functions equivalently to the previous Collection Cup in (1) promoting semen liquefaction, (2) semen homogenization; and (3) generating the equivalent Trak sperm concentration result.

Semen Liquefaction
The objective of this study was to determine the effectiveness of new Volume Cup in promoting semen liquefaction. A total of 20 semen sample aliquots from three semen samples were tested for liquefaction by measuring the volume of semen dispensed by the transfer devices included with the Trak System (250 µL exact volume pipettes) after incubation according to directions.

Summary results
A total of three semen samples were used in this study, with no more than 10 repeat measurements from a single sample. All samples were confirmed as liquefied and non-viscous at 30 minutes. The total average for these volume measures was 253.05 µL, with a 95% CI of 249.60 – 256.00 µL, meeting the acceptance criteria.

The data supports that the Volume Cups are effective at promoting semen liquefaction.

Trak Sperm Concentration Category Result Equivalence Study
The objective of this study was to determine whether samples incubated in the new Volume Cup give equivalent Trak category results to samples incubated in the previous Collection Cup. Two sperm concentrations in the vicinity of the WHO threshold cutoff (15 M/mL) were tested in 20 replicates for each cup type on Trak Props, and results were categorized as ≤ 15 M/mL (Low), 15 – 55 M/mL (Moderate), and > 55 M/mL (Optimal).

Summary results

The following includes summary of results in this study. All conditions were categorized correctly with respect to the reference method at least 90% of the time. Both semen pools were first formulated as a single pool, then divided evenly over the two cup types, and then CASA confirmed for both cups types just before Trak assay initiation.

Nominal Pool Condition	Measured CASA results				Average Concentration of sample	Trak Results ≤ 15 M/mL	Trak Results 15 – 55 M/mL	Trak Results > 55 M/mL
10 M/mL, control	10.2	11.0	11.9	12.3	11.4	20	0	0
10 M/mL, volume cup	10.8	11.4	11.4	13.0	11.7	20	0	0
20 M/mL, control	21.0	17.9	21.8	21.9	20.7	0	20	0
20 M/mL, volume cup	20.0	19.1	19.5	20.2	19.7	0	20	0

Trak results for both the new Volume Cup and the previous Collection cup were correctly categorized with respect to the reference method 100% of the time, exceeding the study acceptance criteria.

Semen Homogenization study

The objective of this study was to determine whether sperm concentration is evenly distributed within the new Volume Cup vs the previous Collection Cup when agitated. Semen samples were formulated to two sperm concentrations differing by more than 50%. Twenty (20) aliquots were taken from the top and bottom of each cup for each pool, and its sperm concentration was accessed.

The two cups performed equivalently.

Summary results

The following includes average results by unique condition, cup type, and grand mean for pools. Sample deviations (SD) are also shown.

Pool ID	Cup Type	Location	n	Mean ± SD (M/mL)	Cup type Mean ± SD (M/mL)	Grand Mean ± SD (M/mL)
A	Collection Cup (Previous)	Top	20	17.1 ± 0.7	17.1 ± 0.7	17.3 ± 0.8
		Bottom	20	17.2 ± 0.7		
	Volume Cup (New)	Top	19	17.5 ± 0.7	17.5 ± 0.8	
		Bottom	20	17.5 ± 0.9		
B	Collection Cup (Previous)	Top	20	36.4 ± 2.2	35.3 ± 2.5	36.1 ± 2.5
		Bottom	20	34.3 ± 2.5		
	Volume Cup (New)	Top	20	36.7 ± 2.6	36.9 ± 2.2	
		Bottom	20	37.1 ± 1.8		

807.92 (b)(2): Brief Description of Clinical Data

Two studies were performed to assess Lay Subject validation for the 1.5 mL reference marking on the new Volume Cup. Users were asked to determine semen volume with respect to 1.5 mL reference mark, where a volume less than 1.5 mL is considered a positive result for hypospermia.

Stage 1 Study: Interpretation of Photographs

The objective of the study was to demonstrate the accuracy of the new Volume Cup as interpreted by the intended users. A total of 232 semen sample photographs were interpreted as ≤ 1.5 mL or

> 1.5 mL by Lay Subjects as well as trained technicians (blinded to the result), and were confirmed with the result obtained by the reference method.

The descriptive demographic statistics for the Lay Subjects (n = 52) were as follows. Subjects were 28.0 years on average (range 18.0 – 68.0), with a high prevalence of male gender (57.7%), Caucasians (44.2%) with some college education (40.4%). We also performed lay user interpretation questionnaire, and a majority (90.4%) of Lay Subjects gave answers indicating an understanding of the instructions according to the intended interpretation.

Summary results

Primary Analysis – Sensitivity and specificity for Lay Subject interpretation

The following includes 2 x 2 contingency table, with study results, for performance estimates of Lay Subjects versus reference method.

		Reference result, n = 232	
		≤ 1.5 mL	*> 1.5 mL*
Lay subject result	*≤1.5 mL*	**98**	**6**
	>1.5 mL	**3**	**125**

The following includes performance parameters for Lay Subject interpretation versus reference method.

Sensitivity, % (95% CI)	Specificity, % (95% CI)
97.0% (91.6 – 99.0%)	95.4 % (90.4 – 97.9%)

Additionally, the overall percent agreement (OPA or "accuracy") was found to be 96.1% (92.8 – 97.9%). For the analysis set, 9 (3.9%) of interpreted results were discordant versus the reference method, with 6 (2.6%) indicating false positive results and 3 (1.3%) indicating false negative results. Of the Lay Subject vs. reference discrepant results, 9 (100%) were within 0.5 mL of the 1.5 mL threshold with reference results, often reading above 1.5 mL.

Trained Technician volume results versus reference results

The following includes 2 x 2 contingency table, with study results, for performance estimates of Trained Technicians versus reference method.

		Reference result, n = 232	
		≤ 1.5 mL	> 1.5 mL
Technician result	*≤1.5 mL*	**100**	**4**
	>1.5 mL	**4**	**124**

The following includes performance parameters for Trained Technician interpretation versus reference method

Sensitivity, % (95% CI)	Specificity, % (95% CI)
96.2% (90.5 – 98.5%)	96.9% (92.2 – 98.8%)

Additionally, the OPA was found to be 96.6% (93.3 – 98.2%). For the analysis set, 8 (3.4%) of interpreted results were discordant versus the reference method, with 4 (1.3%) indicating false negatives and 4 (1.3%) indicating false positive results. Of the Technician vs. reference discrepant results, 8 (100%) were within 0.5 mL of the 1.5 mL threshold.

Trained Technician results versus Lay Subject results

The following includes trained Technician vs Lay Subject interpretation contingency table.

		Trained Technician result, n = 232	
		≤ 1.5 mL	> 1.5 mL
Lay Subject result	*≤1.5 mL*	**100**	**1**
	>1.5 mL	**4**	**127**

The following includes descriptive statistics showing positive percent agreement (PPA), negative percent agreement (NPA) and overall agreement between Lay and Technician interpretation.

OPA, % (95% CI)	PPA, % (95% CI)	NPA, % (95% CI)
97.8% (95.1 – 99.1%)	96.2% (90.5 – 98.5%)	99.2% (95.7 – 99.9%)

Trained technician tended to agree with the Lay Subject more than 95% of the time, with the lower bound of all comparison statistics above 90%. In this analysis set, Technician and Lay Subject disagreed on 5 (2.2%) of the samples.

Stage 2 Study: Interpretation of Simulated Sample in the Volume Cup

The objective of the second study was to assess interpretation and ease of use of the physical Volume Cup filled with known volumes of artificial semen as interpreted by the intended users.

A total of 127 semen sample photographs were interpreted as ≤ 1.5 mL, > 1.5 mL, or Invalid by 32 Lay Subjects. Each Lay Subject interpreted 4 Cups filled with 1 mL, 1.2 mL, 1.8 mL, or 2 mL of artificial semen in random order.

The descriptive demographic statistics for the Lay Subjects (n = 32) were as follows. Subjects were 35.1 years on average (range 25– 59), with a high prevalence of Caucasians (53.1%) with post-graduate education (53.1%).

Summary results

Primary Analysis – Sensitivity and specificity for Lay Subject interpretation

The following includes 2 x 2 contingency table for performance estimates versus reference method with Stage 2 results.

		Reference result, n = 127	
		≤ 1.5 mL	> 1.5 mL
Lay Subject result	*≤1.5 mL*	**60**	**2**
	>1.5 mL	**3**	**62**

The following includes performance parameters for Lay Subject interpretation versus reference method.

Sensitivity, % (95% CI)	Specificity, % (95% CI)
95.2% (86.9-98.4%)	96.9% (89.3-99.1%)

These results suggest that in the hands of Lay Subjects, the Volume Cup with appropriate instructions provides adequate resolution of semen volume in the vicinity of the WHO threshold for hypospermia.

Lay Subject Questionnaire results

Lay Subjects, after completing a volume cup reader study, also completed a Tester Questionnaire with 11 multiple choice questions. Five of the questions were designed to capture the subject's perceptions of ease of use of the Trak device, and the remaining six questions were to gauge interpretation and understandability of the instructions. While slightly more than a quarter of the respondents assigned "somewhat difficult" or "difficult" to the task of finding the liquid level, more than 95% of the responses for interpreting cups were assigned correctly with respect to the reference method. Additionally, a majority (90.6%) of testers gave answers indicating an understanding of the instructions according to the intended interpretation.

CONCLUSIONS

Sandstone Diagnostics, Inc. has performed two cross-sectional studies of a suitable sample sizes to investigate and determine the substantial equivalence of their device to a recognized reference method of semen volume measurement via a calibrated scale. The results of the prospectively stated primary analyses indicate the lower bound of the 95% confidence interval for sensitivity and specificity meeting the pre-specified acceptance criteria. Specifically, Stage 1 resulted in an observed sensitivity of 97.0% (95% CI: 91.6 – 99.0%) and specificity of 95.4% (95% CI: 90.4 – 97.9%) with the lower bound of the 95% confidence intervals meeting the acceptance criteria of ≥ 80% for both sensitivity and specificity. An overall percent agreement ("accuracy") between Lay Subject and Reference method was found to be 96.1% (92.8 – 97.9%). Stage 2 resulted in an observed sensitivity of 95.2% (95% CI: 86.9-98.4%) and specificity of 96.9% (95% CI: 89.3-99.1%), also meeting acceptance criteria. These outcomes provide evidence supporting the accuracy of the Trak volume test when used by lay testers representing the population of intended use.

Further, Trak volume results generated by subjects generally agreed with results from the same specimens tested by trained users, indicating the quality of the instructions for use. Subjects from the Stage 2 study presented with filled cups generally felt the volume cup would be easy to use in terms of procedure and interpretation of results with regard to the clinical threshold of 1.5 mL. In summary, the study demonstrated substantial equivalence of the Trak volume test in comparison to the reference method in the hands of the intended use population.

807.92 (b)(3): Brief Description of Clinical Data

The conclusions drawn from the analytical and clinical data demonstrate that the device is safe and effective for its intended use.