DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2016

Sandstone Diagnostics, Inc.
c/o Erika B. Ammirati
Ammirati Regulatory Consulting
575 Shirlynn Court
Los Altos, CA 94022

Re: K153683
Trade/Device Name: Trak® Male Fertility Testing System
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 14, 2016
Received: April 15, 2016

Dear Ms. Ammirati,

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153683

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. 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.

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 K153683.

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: Greg Sommer, PhD

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

Trade name:
Trak® Male Fertility Testing System

Common Name: Sperm concentration test

Classification: 21 CFR § 864.5220

807.92 (a)(3): Identification of the legally marketed predicate devices
SpermCheck™ Fertility, Princeton Biomedtech Corp, Monmouth Junction, NJ, K100341

807.92 (a)(4): Device Description
The 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 collection cups and sample droppers. 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. 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.

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

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

Comparison	**Subject Device Trak® Male Fertility Testing System**	**Predicate Device SpermCheck® Fertility (K100341)**
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. 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.	SpermCheck® Fertility is a qualitative test that detects sperm concentration at or above 20,000,000 sperm/mL. The test is intended for use as an aid in the determination of a man's fertility status. For in vitro, over the counter home use.
Class	Class II	Same
Regulation Number	21 CFR 864.5220	Same
Product Code	GKZ	Same
Branch	Hematology (81)	Same
Class	Class II	Same
Test type	Semi-Quantitative	Qualitative
Test locale	Home use	Same
Sample type	Human semen	Same

Comparison	Subject Device Trak® Male Fertility Testing System	Predicate Device SpermCheck® Fertility (K100341)
Test reporting	Visual readout of cell column height	Visual line
Test principle	Centrifuged packed cell height	Chromatographic immunoassay
Primary cut-off	15 M/mL (lower reference limit, current WHO guidelines)	20 M/mL (lower reference limit, previous WHO guidelines)
Secondary cut-off	55 M/mL (indication of faster time to pregnancy based on Slama et al 2002 study)	None
Test control method	External Quality Control test solution	Internal control line

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

A series of studies were performed that evaluated the following analytical performance characteristics: analytical sensitivity, precision, interference testing, QC material precision, and cleaning robustness.

Analytical Sensitivity

Near-Cutoff Validation

The objective was to demonstrate that Trak generates results sufficiently close to 15 M/mL and 55 M/mL when samples near each of these cut-offs are tested. Fresh semen samples were pooled and diluted to 7 concentrations that challenged the 15 M/mL threshold. The approximate following concentrations were formulated:

10 M/mL sperm
11.5 M/mL sperm
13 M/mL sperm
15 M/mL sperm (at or near threshold)
17 M/mL sperm
18.5 M/mL sperm
20 M/mL sperm

Similarly, semen samples were pooled and diluted to 7 concentrations that challenge the 55 M/mL threshold. The approximate following concentrations were formulated:

45 M/mL sperm
47 M/mL sperm
50 M/mL sperm
55 M/mL sperm (at or near threshold)
60 M/mL sperm
63 M/mL sperm
65 M/mL sperm

The concentration of each pooled sample was verified to within 5% of target values by CASA and tested in 20 replicates on the Trak System

Summary of supplemental validation, including sum for each category and percent correct calls.

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
1	10.2 ± 0.4	20	0	0	100
2	11.6 ± 0.3	20	0	0	100
3	13.2 ± 0.2	20	0	0	100
4	15.1 ± 0.5	19	1	0	n/a
5	17.1 ± 0.5	3	17	0	85
6	18.3 ± 0.4	0	20	0	100
7	20.8 ± 0.5	0	20	0	100
8	44.0 ± 3.1	0	20	0	100
9	47.0 ± 1.0	0	20	0	100
10	50.6 ± 2.3	0	20	0	100
11	54.1 ± 2.5	0	16	4	n/a
12	59.1 ± 2.2	0	9	11	55
13	62.9 ± 5.2	0	1	19	95
14	66.3 ± 1.1	0	0	20	100

The data support that Trak results are adequately close to reference values in the vicinity of both thresholds.

Precision

The objective of this study was to establish the measurement precision of the Trak system. Three lots of Props were tested in five "days" on 7 sperm samples diluted to concentrations near 15 M/mL and 55 M/mL and were confirmed by CASA. Because sperm cells are not stable over time, time periods within a single day were substituted for days. Each combination of "day", Prop lot/Operator/Instrument, and run were tested in 2 replicates to obtain 60 total replicates per sperm concentration.

Reference Measurements from Precision Study

ID #	Replicate results (M/mL)				Average ± SD (M/mL)
	1	2	3	4	
1	13.1	14.5	12.7	12.7	13.3 ± 0.9
2	15.5	16.4	15.6	14.2	15.4 ± 0.9
3	16.8	16.5	16.7	16.7	16.7 ± 0.1
4	17.9	19.0	17.1	18.6	18.2 ± 0.8
5	42.7	45.0	49.0	46.3	45.8 ± 2.6
6	58.8	59.8	55.2	52.9	56.7 ± 3.2
7	66.4	58.3	59.4	63.6	61.9 ± 3.8

Summary results

The following includes grand averages for each condition, sum for each category, and percent correct calls.

ID	# Trak Results ≤ 15 M/mL	# Trak Results > 15 M/mL		% Correct
		15- 55 M/mL	>55 M/mL	
1	60	0	0	100
2	60	0	0	n/a
3	30	30	0	50
4	18	42	0	70
5	0	60	0	100
6	0	26	34	n/a
7	0	0	60	100

The precision of the Trak device is adequate for meeting the user's need for a consistent semi-quantitative result when used according to instructions.

Consumer interpretation study

The objective was to demonstrate that Trak results are interpreted correctly by lay users, particularly close to the 55 M/mL threshold. Lay, novice subjects at two sites were presented with instructions for use, a Trak Male Fertility System, and a document packet containing an instructional comprehension quiz and images of Trak results for evaluation. Subjects were instructed to read through the instructions and answer all questions in the packet, but were given no further assistance. Images of seven Trak Props representing results at 8 M/mL, 13 M/mL, 20 M/mL, 47 M/mL, 63 M/mL, 70 M/mL, and 85 M/mL were presented in a different randomized order to each subject. Users categorized each result according to their interpretation: ≤15 M/mL, 15-55 M/mL, or > 55 M/mL. Sixty-one (61) subjects (28 male, 33 female) performing a total of 425 Prop interpretations were included in this study. Two (2) interpretation forms were not correctly filled out by each of two subjects, and were excluded from the study. A result below a given threshold was considered to be a positive result (i.e. positive for the condition of low sperm concentration) for the purposes of calculating PPA and NPA.

The subjects assigned the correct category in 414 instances, for an OPA of 97.4%. The results are tabulated below:

User interpretation by Prop result

Prop ID	Trak Result (M/mL)	Correct interpretation	# Correct interpretations	# Total interpretations	Correct (%)	95% CI (%)
A	8	≤ 15 M/mL	59	61	96.7	88.8 - 99.1
B	63	> 55 M/mL	58	60	96.7	88.6 - 99.1
C	20	15 - 55 M/mL	61	61	100.0	94.1 - 100
D	85	> 55 M/mL	59	61	96.7	88.8 - 99.1
E	47	15 - 55 M/mL	59	61	96.7	88.8 - 99.1
F	13	≤ 15 M/mL	60	60	100.0	94.0 - 100
G	70	> 55 M/mL	58	61	95.1	86.5 - 98.3

User interpretation. 3x3 Contingency table

		Reference Value		
		≤ 15 M/mL	15-55 M/mL	> 55 M/mL
Subject Interpretation	≤ 15 M/mL	119	0	3
	15 – 55 M/mL	1	120	4
	> 55 M/mL	1	2	175

Accuracy of interpretation with respect to 55 M/mL

Parameter	**Value**	**95% CI**
PPA	98.8%	96.5 – 100%
NPA	96.2%	91.6 – 100%

The study met all acceptance criteria. The data support that lay users are able to interpret the Trak results.

Interference Testing

The objective of this study was to determine the effect of potential interfering substances on Trak results. The study evaluated elevated concentrations of saliva, urine, blood, leukocytes, *E. coli*, *C. albicans*, *C. trachomatis*, *N. perflava*, testosterone, D-norgestrel, and β-estradiol as interfering substances in the Trak test. The pathological concentrations tested were derived from literature or WHO standards, where appropriate. Each concentration of interfering substance was spiked into semen containing approximately 10 M/mL sperm or 20 M/mL sperm, and tested alongside control semen where there was the absence of interfering substances. Each of these conditions was tested in 20 replicates on the Trak device alongside and evaluated against the 15 M/mL threshold, then immediately photographed in the presence of a calibrated ruler for quantitative analysis.

Each interfering substance was also spiked into semen samples of approximately 45 M/mL sperm or 65 M/mL sperm and tested alongside control semen in the absence of the interfering substances. Each of these conditions was tested in 10 replicates on the Trak device, photographed in the presence of a calibrated ruler, and evaluated against the 55 M/mL threshold.

Summary of Microbial Interference, including sum for each category and percent correct calls.

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
1a	10.03	20	0	0	100 %
2	9.43	20	0	0	100 %
3	9.55	20	0	0	100 %
4	9.23	20	0	0	100 %
5	10.75	20	0	0	100 %
6a	19.50	1	19	0	95 %
7	20.13	0	20	0	100 %
8	19.43	0	20	0	100 %
9	19.48	0	20	0	100 %
10	19.43	2	18	0	90 %
11a	47.8	0	10	0	100 %
12	46.2	0	10	0	100 %
13	48.6	0	10	0	100 %
14	47.0	0	10	0	100 %
15	48.4	0	10	0	100 %
16a	68.7	0	0	10	100 %
17	67.3	0	0	9	100 %
18	66.8	0	0	10	100 %
19	63.9	0	0	9	100 %
20	68.6	0	0	10	100 %
1b	10.9	20	0	0	100 %
6b	20.2	0	20	0	100 %
11b	42.9	0	10	0	100 %
16b	63.6	0	0	10	100 %
21	10.4	20	0	0	100 %
22	10.5	20	0	0	100 %
23	12.3	20	0	0	100 %
24	12.3	20	0	0	100 %
25	19.6	0	20	0	100 %
26	20.0	1	19	0	95 %
27	18.3	0	20	0	100 %
28	18.3	0	20	0	100 %
29	43.7	0	9	0	100 %
30	45.9	0	9	1	90 %
31	47.0	0	9	0	100 %
32	47.0	0	10	0	100 %
33	63.1	0	0	10	100 %
34	63.1	0	0	10	100 %
35	61.9	0	0	10	100 %
36	61.9	0	0	9	100 %

Summary of Saliva Interference- including sum for each category and percent correct calls.

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
1	10.4	20	0	0	100 %
2	10.1	20	0	0	100 %
3	20.5	0	19	0	100 %
4	19.8	0	20	0	100 %
5	42.2	0	10	0	100 %
6	43.9	0	10	0	100 %
7	67.3	0	0	10	100 %
8	63.7	0	0	10	100 %

Summary of Urine Interference data- including sum for each category and percent correct calls.

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 (M/mL)	> 55 M/mL	
1	10.1	20	0	0	100 %
2	10.6	20	0	0	100 %
3	21.0	0	20	0	100 %
4	21.2	0	20	0	100 %
5	43.8	0	10	0	100 %
6	41.0	0	10	0	100 %
7	66.2	0	0	10	100 %
8	61.1	0	0	10	100 %

Summary of Leukocyte Interference-including averages for each condition, sum for each category, and percent correct calls.

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
1	10.6	20	0	0	100 %
2	10.8	20	0	0	100 %
3	11.0	9	11	0	45 %
4	21.9	0	20	0	100 %
5	21.7	0	20	0	100 %
6	20.1	0	20	0	100 %
7	43.9	0	10	0	100 %
8	41.0	0	10	0	100 %
9	43.5	0	10	0	100 %
10	66.2	0	0	10	100 %
11	63.0	0	0	10	100 %
12	65.9	0	0	10	100 %

Summary of Blood Interference, including sum for each category and percent correct calls

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
1	9.9	20	0	0	100 %
2	10.1	20	0	0	100 %
3	10.3	20	0	0	100 %
4	20.1	0	20	0	100 %
5	20.7	0	19	0	100 %
6	20.7	0	20	0	100 %
7	42.2	0	10	0	100 %
8	45.5	0	10	0	100 %
9	45.6	0	10	0	100 %
10	67.3	0	0	10	100 %
11	64.4	0	0	10	100 %
12	66.9	0	0	10	100 %
13	8.7	0	10	0	0 %
14	39.5	0	0	10	0 %
15	10.0	10	0	0	100 %

Summary of hormone interference, including sum for each category and percent correct calls.

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
1	10.2 ± 0.6	20	0	0	100
2		20	0	0	100
3		20	0	0	100
4		20	0	0	100

ID #	CASA Result (M/mL)	# Trak ≤15 M/mL	# Trak >15 M/mL		% Correct
			15 – 55 M/mL	> 55 M/mL	
5	21.5 ± 0.5	0	20	0	100
6		0	20	0	100
7		0	20	0	100
8		0	20	0	100
9	43.5 ± 2.9	0	10	0	100
10		0	10	0	100
11		0	10	0	100
12		0	10	0	100
13	64.1 ± 2.0	0	0	10	100
14		0	1	9	90
15		0	0	10	100
16		0	0	10	100

Bacteria associated with sexually transmitted diseases and elevated hormone levels were found to not interfere with Trak results at the relevant concentrations. Of the tested interferents, only 3 M/mL leukocytes and 1% whole blood failed acceptance criteria for any tested concentration. One percent (1%) whole blood produces an obvious red contamination of the pellet and can be addressed by appropriate labeling. A limitation will be added to the labeling stating that extremely high levels of leukocytes in the semen sample may produce falsely elevated results.

QC Material Precision

The objective of this study was to establish the precision of the Trak QC material. Two lots each of two formulations of QC material intended to give Trak results of approximately 17.5 M/mL (Control Solution A) and 7.5 M/mL (Control Solution B) were each tested in duplicate in two separate runs per day over 20 non-consecutive days.

Summary of Results

Describes percent correct calls for each QC formulation.

QC Material formulation	# above 15 M/mL	# below 15 M/mL	% correct calls
A	160	0	100%
B	0	160	100 %

Both formulations of the Trak QC material meet acceptance criteria, with 100% of results falling in the expected category. This data supports that the Trak QC material has adequate precision to meet the user's need for a consistent means of testing the reliability of the device and "practicing" the test.

Cleaning Robustness

The objective of this study was to assess whether the Trak Engine performs adequately after repeated cycles of cleaning and disinfection as would occur during end-use. Trak Props were tested in replicates of 10 with 4 different sperm concentrations intended to challenge the 15 M/mL threshold and 55 M/mL feature: approximately 10 M/mL, 20 M/mL, 45 M/mL and 65 M/mL. One set of Props was tested before cleaning and disinfection, and one set of Props was tested after 50 cycles of cleaning with soap and water and disinfection with Super Sani-Wipes, according to the proposed user instruction. Engine spin rates were checked against specifications before and after cleaning and disinfection.

Trak Results from Cleaning Study
(4 levels, pre and post clearing)

ID # 1 (10 M/mL pre-cleaning)	ID # 2 (10 M/mL post-cleaning)	ID # 3 (20 M/mL pre-cleaning)	ID # 4 (20 M/mL post-cleaning)
Trak category result	**Trak category result**	**Trak category result**	**Trak category result**
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL
≤ 15M/mL	≤ 15M/mL	> 15 M/mL	> 15 M/mL

ID # 5 (45 M/mL pre-cleaning)	ID # 6 (45 M/mL post-cleaning)	ID # 7 (65 M/mL pre-cleaning)	ID # 8 (65 M/mL post-cleaning)
Trak category result	**Trak category result**	**Trak category result**	**Trak category result**
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL
> 15 M/mL	> 15 M/mL	> 15 M/mL	> 15 M/mL

Reference (CASA) Results for ID Samples 1-8

ID #	Replicate results (M/mL)				Average ± SD (M/mL)
	1	2	3	4	
1	10.3	9.3	9.8	9.1	9.6 ± 0.5
2	9.6	10.0	10.1	9.8	9.9 ± 0.2
3	20.5	21.5	21.5	20.1	20.9 ± 0.7
4	20.6	21.0	21.8	20.5	21.0 ± 0.6
5	45.0	45.8	45.3	48.0	46.0 ± 1.4
6	39.5	42.8	42.4	43.2	42.0 ± 1.7
7	66.2	65.4	58.7	64.6	63.7 ± 3.4
8	67.2	58.8	64.9	63.2	63.5 ± 3.6

The following data illustrate the measured spin rates for each Engine used in this study, before and after 50 cleaning cycles. Heavy cleaning had little effect on Engine spin rate.

Engine	Pre/Post Clean	Replicate RPM				Average RPM ± SD
43	Pre	7448	7371	7373	7262	7360 ± 67
	Post	7107	7239	7301	7378	7278 ± 111
57	Pre	7664	7549	7642	7577	7592 ± 58
	Post	7537	7564	7594	7522	7538 ± 46
61	Pre	7508	7514	7479	7428	7456 ± 68
	Post	7251	7280	7326	7296	7289 ± 27
64	Pre	7046	7578	7697	7663	7517 ± 268
	Post	7457	7576	7506	7601	7531 ± 58
94	Pre	6958	6900	6834	6788	6847 ± 83
	Post	6880	6940	6940	6957	6935 ± 32

Summary of Results

ID #	CASA Result (M/mL)	#Trak Results ≤ 15 M/mL	#Trak Results > 15 M/mL		% Correct
			15-55	> 55	
1	9.6	10	0	0	100 %
2	9.9	10	0	0	100 %
3	20.9	0	10	0	100 %
4	21.0	0	10	0	100 %
5	46.0	0	9	1	90 %
6	42.0	0	9	1	90 %
7	63.7	0	0	10	100 %
8	63.5	0	0	10	100 %

The data support the resistance of the Trak Engine to the intended cleaning and disinfection protocol.

Prop Stability

Real time stability testing was performed. Three lots of Trak Props were packaged according to manufacturing procedures, then tested after specific time periods had elapsed. At the end of each time period (time point), 20 Props each were tested with concentrations of approximately 10 M/mL and 20 M/mL and visually evaluated against the 15 M/mL threshold. At least 90% of test results at each sperm concentration were required to fall in the correct category. At each time point, one Prop from each lot was tested on cell-free seminal plasma as a control. All samples were freshly prepared from pooled and diluted semen samples at each test time point. In order to validate the freshly composed samples, 5 replicates from each of the 10 M/mL and 20 M/mL samples were tested on Props assembled within 30 days of the tested time point.

Stability data meeting acceptance criteria were obtained for one time point beyond the claimed expiry date for the Trak Props.

QC Material Stability

The "Moderate" formulation of the QC material that is designed to show a result just above the 15 M/mL mark was evaluated for stability. Two lots of the "Moderate" formulation of the QC material were packaged according to manufacturing procedures, then tested after specific time periods had elapsed. At the end of each time period (time point), 10 replicates of the control were tested on Trak Props and visually evaluated against the 15 M/mL threshold. At least 90% of test results were required to fall in the correct category.

Stability data meeting acceptance criteria were obtained for one time point beyond the claimed expiry date for the Trak QC material.

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

The objective of the study was to demonstrate the accuracy of the Trak system in the hands of the intended users. The study was a cross-sectional, multi-site investigation conducted at three clinical sites in the United States. Male subjects providing and testing semen specimens were either presumptively healthy (by self-report), a partner in a couple having difficulty conceiving, diagnosed with male factor infertility, post-vasectomy patients, or post-vasectomy reversal patients. Additionally, "tester" lay-persons were recruited to test semen specimens provided by a subset of subjects.

Following collection of the specimen sample by the study subject, either the study subject or the tester analyzed the sample by Trak using only the Trak instructional booklet provided in the kit. After recording their result, a health-care professional (HCP) employed at the study site observed the Prop and recorded their own interpretation of the subject/tester results, and then performed their own Trak test using a saved aliquot of the original semen specimen provided by the subject. The HCP then recorded the result of their test. Lay readers were asked to interpret each result into one of three categories: ≤ 15 M/mL, 15-55 M/mL, or > 55 M/mL according to the product instructions. Prior to completing the study, all subjects providing and testing their semen specimens, and the testers, completed a Tester Questionnaire of their subjective perspectives of the ease of performing the Trak procedure, including interpretation of results.

In parallel to Trak testing, an HCP technician employed at the site analyzed an additional aliquot of the original semen specimen on a Computer Aided Semen Analysis (CASA, Hamilton-Thorne CEROS™ Computer Aided Semen Analysis system) instrument and recorded their results in M/mL. Study subjects, testers, and reference method operators were blinded to the test results from the other testers during the clinic visit.

The descriptive demographic statistics for the subjects providing semen specimens for analysis (n = 239) were as follows. Subjects were 33.9 years on average (range 20.0 – 49.0), with a high prevalence of Caucasians (51.9%) with some college education (33.1%). The demographic distributions for the testers who tested samples provided by the subjects were as follows. Testers were 31.8 years on average (range 24.0 – 45.0), completely of female gender, with a high prevalence of Caucasians (63.6%) with some college education (45.5%).

Analysis of performance

The figure below presents the results of the 3 x 3 contingency table comparing Trak results from the subject/tester to the CASA reference method using data across all three study sites (N=239). This is followed by the calculated point estimates and Wilson Score 95% CIs for conditional probability of a correct Trak result for each result category (≤ 15 M/mL, 15-55 M/mL, or > 55 M/mL) across all sites.

The results indicate conditional probability of 93.3% (84.1-97.4%) for results categorized as ≤ 15 M/mL, 82.4% (73.3-88.9%) for results categorized as 15-55 M/mL, and 95.5% (88.9-98.2%) for results categorized as >55 M/mL when utilizing results across all three study sites.

3 x 3 contingency table for agreement between Subject/Tester Trak results vs. CASA all study sites (N=239)

		Reference Value		
		≤ 15 M/mL	15-55 M/mL	> 55 M/mL
Subject Interpretation	≤ 15 M/mL	56	8	1
	15 – 55 M/mL	4	75	3
	> 55 M/mL	0	8	84

Summary of performance parameters – Subject/tester Trak results vs. CASA across all study sites (N=239)

Category	Conditional probability	95% CI
≤ 15 M/mL	93.3%	84.1 – 97.4%
15 – 55 M/mL	82.4%	73.3 – 88.9%
> 55 M/mL	95.5%	88.9 – 98.2%

Tester Questionnaire results

Subjects providing semen specimens and testing their specimens, as well as testers analyzing provided semen specimens, completed a Tester Questionnaire. The Questionnaire incorporated 11 multiple choice questions targeted to capture the subject's or testers' subjective perceptions of ease of use of the Trak device, including interpretation of results. Eight (8) of the questions were designed as statements regarding ease of use followed by a 5-point Likert Scale from which the subject/tester chose from responses of very easy, somewhat easy, neutral, somewhat difficult, or difficult. The remaining three questions dealt with yes/no responses to statements regarding interpretation of result. Results generally demonstrate ease of use of the Trak test from the subject/tester's perspective, with only the occasional "somewhat difficult" or "difficult" response. Additionally, a majority (98.7%) of testers concluded that they performed the steps correctly and got a correct result.

CONCLUSIONS

Sandstone Diagnostics, Inc. has performed a multi-site, cross-sectional clinical study of a suitable sample size to investigate and determine the substantial equivalence of their device to a recognized reference method of sperm cell concentration via an FDA-cleared CASA system. Observed conditional probability of a correct Trak result was 93.3% (84.1-97.4%) for results categorized as ≤ 15 M/mL, 82.4% (73.3-88.9%) for results categorized as 15-55 M/mL, and 95.5% (88.9-98.2%) for results categorized as >55 M/mL. These outcomes provide evidence supporting the accuracy of the Trak test when used by lay testers, including subjects providing semen specimens and testers, both of whom represent the population of intended use.

Subjects and testers also generally felt the Trak test was easy to use in terms of procedure and interpretation of results. In summary, the study demonstrated substantial equivalence of the Trak system in comparison to the reference method and its safe use in the hands of the intended use population.