K963197

510(k) SUMMARY

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1. **Submitter:** ANSYS, Inc.

   Address: 2 Goodyear
   Irvine, CA 92618

   Telephone: (714) 770-9381 Ext. 7915

   Contact Person: Lorna Gamboa

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2. **Trade Name :** ON•SITE Alcohol

   Common Name: Alcohol Test System

   Classification: Class II

3. **Predicate Device Information:**

   The modified ON•SITE Alcohol test is being compared to its predecessor, the current ON•SITE Alcohol, both manufactured by ANSYS, Inc.

4. **Description of the Device:**

   ON•SITE Alcohol is a self contained, disposable enzymatic test device that provides rapid detection of alcohol in saliva or urine. It includes all reagents and supplies necessary to perform the test.

5. **Intended Use:**

   ON•SITE Alcohol is recommended for professional use only and is not intended for over-the-counter sale to the general public. Professional use includes applications in healthcare, corrections and drug treatment.

   ON•SITE Alcohol yields only a "qualitative" result. A positive result indicates that alcohol (ethanol) is present at a concentration of approximately 0.02% when performed according to the instructions.

   Confirmation of ON•SITE Alcohol results using gas chromatography is recommended if quantitative results are desired.

6. Comparison of technological Characteristics:

The modified ON•SITE Alcohol uses the same technology as its predecessor. The only difference is in the formulation of one of its reagents. It has been modified to increase the reaction time, thus slightly raising the limit of detection.

7. Performance Characteristics and Supportive Data:

Accuracy and Precision

Accuracy and precision of the current and modified device was compared by running twenty replicates of three ethanol controls (0.008%, 0.02% and 0.032% w/v). Tests were timed and results were read at exactly 2 minutes. Results were reported as either positive or negative. In addition, reaction times for each test (i.e., time required to produce an observable positive result) were recorded. The mean, standard deviation and coefficient of variations were calculated and compared.

Results confirmed the desired shift in reaction time and detection levels as follows:

% w/v	No. of Positives		Mean Reaction Time		Coefficient of Variation	
EtOH	current	modified	current	modified	current	modified
0.008	13	0	111 sec	147 sec	10.3%	8.2%
0.020	20	12	81 sec	115 sec	8.3%	8.8%
0.032	20	20	61 sec	100 sec	7.9%	6.7%

Sensitivity

The sensitivity of the current and modified device were also compared. Ten replicates of eight controls were tested using both devices. Reaction times were compared. Again, results confirmed the targeted shift in reaction times.

% w/v	Mean Reaction Time		Difference
EtOH	current	modified	sec
0.005	1 min 47 sec	2 min 41 sec	54
0.0075	1 min 33 sec	2 min 14 sec	41
0.01	1 min 19 sec	2 min 10 sec	51
0.0125	1 min 21 sec	1 min 53 sec	32
0.015	1 min 19 sec	1 min 42 sec	23
0.0175	1 min 12 sec	1 min 47 sec	35
0.02	1 min 6 sec	1 min 41 sec	35
0.0225	1 min 6 sec	1 min 29 sec	23