510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k160613

B. Purpose for Submission:

New device

C. Manufacturer and Instrument Name:

Soberlink Healthcare LLC Soberlink Cellular Device

D. Type of Test or Tests Performed:

Quantitative – electrochemical fuel cell sensor

E. System Descriptions:

1. Device Description:

The Soberlink Cellular Device is a hand-held instrument intended to measure ethanol in breath samples. The front of the device has an LCD screen with two display buttons. The bottom of the device has a micro USB charging port. The USB port is for charging purposes only. The side of the device (from top to bottom) has a camera, a blue status light encased around the mouthpiece port, and a power/select button. A reusable mouthpiece is inserted into the mouthpiece port, once the test is taken, the results are displayed on the LCD screen and sent to the central monitoring station. The Soberlink Cellular Device uses an internal Lithium-ion rechargeable battery

2. Principles of Operation:

The Soberlink Cellular Device is a handheld breath alcohol measurement device with integrated GPS, digital imager, and cellular modem. It is designed to take a deep lung sample of the Users breath, calculate their Blood Alcohol Concentration (BAC), and send the BAC reading, physical location, and digital image of the User to the Sober Sky Web Portal for review.

The Device uses an electrochemical fuel cell that is designed to responds to alcohol. After the User blows into the Device for 4 seconds, their photo is taken and a sample of their breath is drawn into the fuel cell by an automatic pump. A chemical reaction between the alcohol and the fuel cell occurs. This reaction generates an electrical current that is directly related to the amount of alcohol in the sample. The current is then

converted to a Blood Alcohol Concentration (BAC) level and displayed for the User. The relationship between alcohol in a person's deep lung breath and in their blood is previously established using Henry's law, which gives a ratio of 2100:1. After the BAC has been calculated, the Device obtains the User's GPS coordinates and constructs a breath test report that includes the photo, BAC, and location, which may then be uploaded to the Portal.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ___X____ or No _____

   This device has only one mode of operation.

4. Specimen Identification:

   There is no mechanism to identify the specimen.

5. Specimen Sampling and Handling:

   The user provides a sample by blowing into the device.

6. Calibration:

   The device is calibrated at the factory. The manufacturer specifies that the device be recalibrated after 1,500 uses. These intervals are based on calibration stability data collected internally.

7. Quality Control:

   There are no external quality controls available for these types of devices.

8. Traceability:

   Calibration is traceable to a commercially available certified ethyl alcohol solution..

9. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for

this line of product types:

Yes__X_____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR § 862.3050, Breath-alcohol test system

2. Classification:

   Class I, reserved

3 Product code:

   DJZ

4. Panel:

   Toxicology (91)

G. Intended Use:

1. Indication(s) for Use:

   The Soberlink Cellular Device is intended to quantitatively measure alcohol in human breath. Measurements obtained by this Device are used in the diagnosis of alcohol intoxication.

   For Prescription use and OTC use.

2. Special Conditions for Use Statement(s):

   For Over-The-Counter (OTC) use

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   k123470

2. Comparison with Predicate Device:

Similarities		
Item	Candidate Device: Soberlink Cellular Device (k160613)	Predicate: Alcovisor Satellite (k123470)
Intended use	Same	The PAS Alcovisor Satellite Breath Alcohol Analyzer is intended to measure alcohol in human breath
Display	Same	LCD
Sensor	Same	Electrochemical Fuel Cell
Detection Range	Same	0.000-0.400 BAC
Power source	Same	Rechargeable batteries

Differences		
Item	Device	Predicate
Calibration	After 1500 tests	Every 250 tests or every 12 months
Battery Life	3 Days	500 tests on full charge
Mouth Piece	Single Patient Use	Single Use
Exhalation Time	4 seconds	3-5 seconds

I. Special Control/Guidance Document Referenced (if applicable):

- ISO 10993 Part 1: (Biological evaluation of medical devices) Evaluation and testing within a risk management process
- ISO 10993 Part 9: Framework for identification and quantification of potential degradation products
- ISO 10993 Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 14971: Medical devices – Application of risk management to medical devices
- IEC 60825 Part 1: (Safety of laser products) Equipment Classification and requirements
- IEC 60601 Parts 1-6: Medical electrical equipment
- IEC 62366: Application of usability engineering to medical devices
- IEC 60601-1-2 – Medical Electrical Equipment

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

The sponsor performed a consumer study to determine if the consumers could use and interpret the device using only the supplied instructions for use. Results were compared to an evidential breath alcohol tester; BACtrack S80 Pro.

Forty-three (43) participants took their breath alcohol reading with the candidate device, and the results were recorded. Within 1-5 minutes after using the Soberlink Cellular Device, the participants were then asked to provide a breath sample using the evidential device. The breath alcohol concentrations ranged from a BAC of 0.000 to 0.130 by the evidential device. Linear regression analysis of the data showed a slope of1.049, a y-intercept of -0.001 and a correlation coefficient of 0.974.

After the study, participants were asked to answer questions and the results demonstrated that the device was adequately easy to use and interpret.

b. Precision/Reproducibility:

The precision and accuracy of the Soberlink Cellular Device was evaluated at an independent testing laboratory, and followed the protocol of the National Highway Traffic Safety Administration (NHTSA). There were 60 trials performed during this testing, which were comprised of 20 trials at 0.000 BAC, 20 trials at 0.008 BAC, and 20 trials at 0.032 BAC. Blood Alcohol Concentrations are simulated in breath by a breath alcohol sample simulator, which provides an alcohol-in-air test sample with known alcohol concentrations, flow rate, and air composition. The acceptance criteria for this testing were: not more than one result greater than 0.020 at 0.000 BAC, not more than one result greater than 0.020 at 0.008 BAC, and not more than one result less than 0.020 at 0.032 BAC. NOTE: for the purposes of this study, a BAC of 0.020 is used to distinguish a positive from a negative result. The Soberlink Cellular Device met all of the applicable NHSTA requirements for precision and accuracy.

c. Linearity:

The Soberlink Cellular Device will report concentrations from 0.000 to 0.400% BAC. However, the DOT Model Specifications require accuracy and precision testing up to a concentration of 0.032 only; therefore, true linearity over the entire measuring range of the device was not evaluated (similar to other cleared BAC measurement devices). Results of linearity assessment were acceptable.

d. Carryover:

Carryover studies are not required by NHTSA and were not performed using these

devices.

e. Interfering Substances:

Testing with cigarette smoke was performed to assess any possible interference. Five trials were performed at 0.000 BAC. An alcohol free individual who smokes cigarettes was appropriate for this trial. The subject was asked to smoke approximately one half of a cigarette. Within one minute after smoking, or after a waiting period specified in the manufacturer's instructions*, the subject performed the breath alcohol test according to the manufacturer's instructions. The subject was then asked to smoke another inhalation and repeat the test to produce a total of five trials. For the purposes of this study, a BAC of 0.020 is used to distinguish a positive from a negative result. The Soberlink Cellular Device had no positive results.

*The sponsor's labeling recommends the user wait 20 minutes after consuming alcohol, smoking, or eating to test a breath sample.

2. Other Supportive Instrument Performance Data Not Covered Above:

a. Limit of Detection

The device was tested at a BAC of zero (blank reading) to assess the possibility of false positives. This consisted of 20 trials under normal laboratory conditions at a BAC of 0.000. Non-alcoholic human breath was used as the sample. The Soberlink Cellular Device had no false positive results in this trial.

b. High/Low Ambient Temperature

Testing at 10°C and 40°C was performed to assess any possible effects of temperature. The testing and acceptance criteria for the processes were: 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. The acceptance criteria were: not more than one result greater than 0.020 using 0.008 BAC, and not more than one result less than 0.020 using 0.032 BAC. NOTE: for the purposes of this study, a BAC of 0.020 is used to distinguish a positive from a negative result. The Soberlink Cellular Device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

c. Vibration

Vibration testing was performed to assess any possible vibrational effects. Twenty trials were performed at 0.008 BAC and 0.032 BAC. The acceptance criteria were: not more than one result greater than 0.020 using 0.008 BAC, and not more than one result less than 0.020 using 0.032 BAC. NOTE: for the purposes of this study, a BAC of 0.020 is used to distinguish a positive from a negative result. The Soberlink Cellular Device had no positive results at 0.008 BAC and no non-positive results at 0.032 BAC.

d. Cutoff

For the purposes of performance testing, a BAC cutoff of 0.020 was used to distinguish positive from negative samples.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.