DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

SOBERLINK HEALTHCARE LLC
C/O ELISA MALDONADO-HOLMERTZ
OBELIX CONSULTING, LLC
12416 FAIRFAX RIDGE PLACE
AUSTIN TX 78738

July 14, 2016

Re: k160613
Trade/Device Name: Soberlink Cellular Device
Regulation Number: 21 CFR 862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: I, Reserved
Product Code: DJZ
Dated: June 10, 2016
Received: June 13, 2016

Dear Elisa Maldonado-Holmertz:

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 regulations (21 CFR Parts 801 and 809), 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" (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.

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,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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)*
K160613

Device Name
Soberlink Cellular Device

Indications for Use *(Describe)*

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.

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
for
Soberlink Cellular Device

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

10 June 2016

4. Device Identification

Trade/Proprietary Name:	Soberlink Cellular Device
Common/Usual Name:	Alcohol Breath Analyzer
Classification Name:	Devices, breath trapping, alcohol
Classification Regulation:	862.3050 – Breath-alcohol test system
Product Code:	DJZ
Device Class:	Class I
Classification Panel:	Toxicology

5. Legally Marketed Predicate Device(s)

K123470 – PAS Breath Analyzer

6. Device Description

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 User's breath, calculate their Blood Alcohol Level (BAC), and send the BAC reading, physical location, and digital image of the User to the Sober Sky Web Portal and Device screen for review.

7. Intended Use and Indications for Use Statement

Intended Use
The Soberlink Cellular Device is intended to quantitatively measure alcohol in human breath.

Indications for Use
Measurements obtained by this device are used in the diagnosis of alcohol intoxication.

For Prescription use and OTC use.

8. Substantial Equivalence Discussion

The following table compares the Soberlink Cellular Device and Sober Sky Web Portal to the predicate device with respect to intended use, technological characteristics, and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 3A – Comparison of Characteristics

Manufacturer	**Soberlink**	**PREDICATE**
Trade Name	**Soberlink Cellular Device**	**PAS Alcovisor Satellite Breath Alcohol Analyzer**
510(k) Number	None	K123470
Product Code	DJZ	DJZ
Regulation Number	862.3050	862.3050
Regulation Name	Breath-alcohol test system.	Breath-alcohol test system.
Indications for Use	Intended Use The Soberlink Cellular Device is intended to quantitatively measure alcohol in human breath. Indications for Use Measurements obtained by this device are used in the diagnosis of alcohol intoxication.	The PAS Alcovisor Satellite Breath Alcohol Analyzer is intended to measure alcohol in human breath. Measurements obtained by this device are used in the diagnosis of alcohol intoxication.
RX and OTC	For Prescription use and OTC use.	OTC
Mouth Piece	Multiple use disposable	Single use disposable
Display	LCD	LCD
Sensor	Electrochemical Fuel Cell	Electrochemical Fuel Cell

Calibration	after every 1500 tests	every 250 tests or every 12 months
Traceability	Each device is calibrated to .038 +/- 0.002 BAC (103ppm) dry gas which is traceable by lot number associated with a certificate of analysis from the manufacturer of the dry gas.	Each device is calibrated to a 0.100% certified wet bath simulator solution which is traceable by lot number associated with a certificate of analysis from the manufacturer of the solution.
Detection Range	0.000 – 0.400 BAC	0.000 – 0.400 BAC
Exhalation Time	4 seconds	3-5 seconds
External Material	Medical grade plastics	Medical grade plastics
Sterile	No	No
Single-Use	No	No
AC Powered	No	Yes – 3 AA Batteries and rechargeable battery
USB Charger (compliant to EN60950, UL and CE)	Yes	No
Battery Life	5-7 days	500 test on full charge
DOT Tested	Yes	Yes
LED Tested (compliant to IEC 62471)	Yes	No
Complies with ISO 10993-1	Yes	Yes
60601, EMC & Electrical Safety Testing Passed	Yes	Yes

9. Non-Clinical Performance Data

Accuracy
The sponsor performed a study to determine if intended (lay) users – untrained study participants - who had consumed alcohol could correctly use and interpret the device using only the supplied instructions for use. Results were compared to an evidential breath alcohol tester (the BACtrack S80 Pro).

Forty-three (43) participants took their breath alcohol reading with the candidate device and recorded the result. Immediately afterward, the participants were administered a breath alcohol test using the evidential device. There were neither device performance failures nor any subject who could not provide a BAC test from each device. Soberlink (M = 0.0426, SD = 0.0278) and BACtrack (M = 0.0417, SD = 0.0262) displayed an average difference of -0.0009 (SD = 0.0047). Regression results indicated a non-significant difference of -0.001 between the two measures with a level of agreement of $\beta = 0.987$ and $R2 = 0.974$.

Precision/Reproducibility
DOT Testing was conducted in accordance to the NHTSA Docket No. 2008-0030 published in 73 FR 16956. This testing included accuracy and repeatability of the Soberlink Cellular Device in comparison to the predicate device, the PAS Alcovisor Satellite.

Interfering Substances
Additionally, the bench testing included cigarette smoke interference, high and low ambient temperature, air blank reading, and vibration. The Soberlink Cellular Device "passed" all testing.

As part of demonstrating safety and effectiveness of Soberlink Cellular Device and in showing substantial equivalence to the predicate device that is subject to this 510(k) submission, Soberlink completed a number of tests. The Soberlink Cellular Device meets all the requirements for overall design, EMC testing and electrical safety confirms that the output meets the design inputs and specifications. The Soberlink Cellular Device passed all testing stated above as shown by the acceptable results obtained.

10. Clinical Performance Data

Randomized clinical trials are not applicable as the innovative aspects introduced are well established. Alcohol breathalyzers have been on the market for many years with no significant incidents of safety or efficacy for the predicate devices. The design, development and testing of Soberlink Cellular Device has not resulted in the need for any randomized clinical trials; however a Usability Study was conducted to determine the impact of human factors. The results indicate that users can comprehend the instructions for use and packaging without additional support in order to utilize the product correctly and safely, and produce a breath sample.

11. Statement of Substantial Equivalence

Based upon the 510(k) summary, 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the subject device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetics Act.

It has been shown in this 510(k) submission that the difference between the Soberlink Cellular Device and Sober Sky Web Portal and the predicate device do not raise any questions regarding its safety and effectiveness. The Soberlink Cellular Device, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.