September 15, 2025

Sober IP LLC
℅ Shadeed Salem
President
Synergy Bioscience
10944 Alder Cir
Dallas, Texas 75238

Re: K250609
Trade/Device Name: Sober Self-Test
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol Test System
Regulatory Class: Class II
Product Code: DIC
Dated: July 29, 2025
Received: July 29, 2025

Dear Shadeed Salem:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S

Digitally signed by JOSEPH A. KOTAREK -S
Date: 2025.09.15 14:59:25 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250609

Device Name
SOBER SELF-TEST

Indications for Use *(Describe)*
SOBER SELF-TEST is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative blood alcohol concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in-vitro diagnostic use. The assay is a disposable test for one-time 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Sober IP LLC
Applicant Address	27694 Franklin Rd Southfield MI 48034 United States
Applicant Contact Telephone	248-506-5107
Applicant Contact	Mr. Timothy Downey
Applicant Contact Email	tim@soberselftest.com
Correspondent Name	Synergy Bioscience
Correspondent Address	10944 Alder Cir Dallas TX 75238 United States
Correspondent Contact Telephone	408-228-7193
Correspondent Contact	Mr. Shadeed Salem
Correspondent Contact Email	shadeed.salem@synergybioscience.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	Sober Self-Test
Common Name	Alcohol test system
Classification Name	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method
Regulation Number	862.3040
Product Code(s)	DIC

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K121256	Alco-Screen® 02	DIC

Device Description Summary 21 CFR 807.92(a)(4)

Sober Self-Test® strips are a visually read qualitative test for the detection of alcohol concentration in saliva. It consists of a visually interpreted test strip that develops a distinct blue color on the test pad when wet with human saliva that has a Alcohol Concentration (AC) equal to or greater than 0.02%. The device consists of a single test in a foil packet or in boxes of three, six, twelve, or 24 boxes of single test packets, each designed for one-time use only.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

SOBER SELF-TEST is a qualitative screening test used to detect the presence of ethyl alcohol in human saliva. The test detects relative blood alcohol concentrations (BAC) greater than or equal to 0.02%. Results are used for the diagnosis of alcohol intoxication. For in-vitro diagnostic use. The assay is a disposable test for one-time use.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Indications for use are similar.

Technological Comparison 21 CFR 807.92(a)(6)

The Sober Self-test is similar to the predicate device, as both employ a qualitative method to detect alcohol in human saliva. Both devices utilize the enzyme Alcohol oxidase in a chromogenic reaction, leading to a color change for result interpretation. Both tests are over the counter single use for in vitro diagnosis. Performance testing confirms that the design differences do not introduce new concerns regarding safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Comparative studies were conducted with a predicate device and demonstrated the substantial equivalence of the device