August 25, 2026

Beacon Biosignals, Inc.
Tahir Rizvi
Vice President, Regulatory Affairs
22 Boston Wharf Rd.
7th Floor, Unit 41
Boston, Massachusetts 02210

Re: K261747
Trade/Device Name: Report Studio
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV
Dated: May 27, 2026
Received: May 27, 2026

Dear Tahir Rizvi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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); 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 Management System Regulation (QMSR) (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,

Patrick Antkowiak -S

Patrick Antkowiak
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K261747 |

Please provide the device trade name(s).

Report Studio

Please provide your Indications for Use below.

Report Studio is a web-based software-only medical device indicated for use in diagnostic evaluation by qualified healthcare professionals to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related disorders.

Report Studio supports the display, review, and manual scoring of physiological recordings containing cardiopulmonary, electroencephalographic (EEG), and/or other polysomnographic (PSG) signals. Report Studio supports display and user adjudication of recording metadata and annotations, can report basic statistical information regarding such content, and can aid in the generation of summary reports from user input, but does not itself independently provide automated sleep staging or similar capabilities.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

# 510(K) SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

| | |
|---|---|
| **Submitter** | |
| **Date Prepared** | August 16, 2026 |
| **510(k) Number** | K261747 |
| **Device Manufacturer** | **Beacon Biosignals, Inc.**<br>22 Boston Wharf Road<br>7th floor, Unit 41<br>Boston, MA 02210<br>United States of America |
| **Primary Contact Person** | Tahir Rizvi, Vice President of Regulatory Affairs<br>Email: tahir.rizvi@beacon.bio<br>Phone: +1 925 577 7605 |
| **Device Information** | |
| **Device Name/Trade Name** | Report Studio |
| **Regulation Number** | 21 CFR 882.1400 (Electroencephalograph) |
| **Classification** | Class II |
| **Device** | Standard Polysomnograph With Electroencephalograph |
| **Product Code** | OLV |
| **510(k) Review Panel** | Neurology |
| **Predicate Device** | |
| **Predicate Manufacturer** | **Nox Medical ehf**<br>Katrinartuni 2,<br>IS - 105 Reykjavik, Iceland |
| **Predicate Device/Trade Name** | Noxturnal Web |
| **Predicate 510(k)** | K241288 |

# 1. DEVICE DESCRIPTION

Report Studio is a software-only medical device (SaMD) delivered as a web-based application, intended for use by qualified healthcare professionals including sleep physicians, interpreting physicians, and Registered Polysomnographic Technologists (RPSGTs), in a supervised clinical environment. The device is indicated for diagnostic evaluation to assess sleep quality and as an aid in the diagnosis of sleep and respiratory-related disorders. It supports the display, review, and manual scoring of physiological recordings containing cardiopulmonary, electroencephalographic (EEG), and/or other polysomnographic (PSG) signals.

Report Studio operates through two integrated software modules. The **Signal Viewer** renders biosignal data with flexible navigation modes, adjustable display settings, and tools for epoch-by-epoch manual sleep staging (Wake, N1, N2, N3, and REM per AASM guidelines) and event editing, including the ability to add, move, and delete scored events on any channel. The **Report Builder** enables clinicians to compile findings, enter interpretive text, reuse saved text snippets, collaborate via section-level comments, apply a digital signature, and export a finalized PDF report. The device performs basic statistical calculations on user-adjudicated annotations but does not autonomously generate clinical conclusions or perform automated sleep staging.

# 2. INTENDED USE/INDICATIONS FOR USE

**Intended Use:**

Report Studio is intended to be used by qualified healthcare professionals to display, review, and analyze physiological signals collected during sleep studies. It is a software-only medical device that provides tools to assist in the assessment of sleep quality and in the diagnosis of sleep and respiratory-related sleep disorders. Report Studio supports manual adjudication of metadata and annotations, and calculations of basic statistical information regarding such content. The device is intended for use in a clinical environment under the supervision of a qualified clinician.

**Indications for Use:**

Report Studio is a web-based software-only medical device indicated for use in diagnostic evaluation by qualified healthcare professionals to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related disorders.

Report Studio supports the display, review, and manual scoring of physiological recordings containing cardiopulmonary, electroencephalographic (EEG), and/or

other polysomnographic (PSG) signals. Report Studio supports display and user adjudication of recording metadata and annotations, can report basic statistical information regarding such content, and can aid in the generation of summary reports from user input, but does not itself independently provide automated sleep staging or similar capabilities.

## 3. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Report Studio and the predicate device, Noxturnal Web (K241288), share the same fundamental intended use and technological characteristics in all clinically material respects. Both are web-based, software-only medical devices indicated for use by qualified healthcare professionals to display, review, manually score, and generate clinical reports from pre-recorded physiological sleep study data, as an aid in assessing sleep quality and diagnosing sleep and respiratory-related disorders in a supervised clinical environment. Neither device performs autonomous scoring or diagnosis and for both medical devices, the clinician retains full responsibility for interpretation and clinical conclusions.

Technologically, the two devices are equivalent across all relevant dimensions. Both accept physiological inputs (EEG, EOG, EMG, ECG, respiratory effort, airflow, oxygen saturation, and body position/activity), provide a multi-channel signal viewer for navigating and configuring pre-recorded sleep data, support manual sleep staging across all AASM-defined stages (Wake, N1, N2, N3, and REM), enable manual annotation of respiratory and arousal events, calculate AASM-standardized indices including the AHI, and generate clinician-authored reports with digital signature. Both operate as cloud-based software accessible via modern internet browsers, requiring no installation on the user's computing machine. There are no significant differences in technological characteristics between the two medical devices. A substantial equivalence table is provided in **Table 1**.

## 4. NONCLINICAL TESTING

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance "Content of Premarket Submission for Device Software Functions" (issued June 14, 2023) for devices classified as "Basic" Level of Concern as defined in the Guidance.

Report Studio was developed and tested in accordance with Beacon Biosignals' Quality Management System. Software documentation generated as part of the design process included:

- Software/Firmware Description
- Risk Management File
- Software Requirements Specifications

- System and Software Architecture
- Software Lifecycle Process Description
- Software Testing as Part of Verification and Validation
- Software Version/Revision Level History
- Unresolved Software Anomalies
- Cybersecurity

## 5. CLINICAL TESTING

Clinical data was not relied upon for a determination of substantial equivalence.

## 6. CONCLUSION

Report Studio is substantially equivalent to the predicate device, Noxturnal Web (K241288). Report Studio has the same intended use as the predicate device. Many of the technological characteristics are the same for the subject and predicate devices. The differences in technological characteristics between the subject and predicate devices, including the absence of an age restriction on the indicated patient population of Report Studio, do not raise new questions of safety or effectiveness. The results of the comparative analysis, software and performance testing validate that Report Studio meets its pre-specified requirements, performs as intended, and is as safe and effective as the predicate device. Therefore, it is determined that Report Studio is substantially equivalent to Noxturnal Web (K241288).

# Table 1: Substantial Equivalence Table

| Category | Subject Device: Report Studio | Predicate Device: Noxturnal Web (K241288) | Comparison |
|---|---|---|---|
| **Description** | | | |
| **Manufacturer** | Beacon Biosignals, Inc. | Nox Medical ehf | N/A |
| **Regulation Description** | 21 CFR 882.1400 | 21 CFR 882.1400 | Same |
| **Regulation Name** | Electroencephalograph | Electroencephalograph | Same |
| **Regulatory Class** | Class II | Class II | Same |
| **Product Code** | OLV | OLV | Same |
| **Comparison of Intended and Indications of Use** | | | |
| **Intended Use** | Report Studio is intended to be used by qualified healthcare professionals to display, review, and analyze physiological signals collected during sleep studies. It is a software-only medical device that provides tools to assist in the assessment of sleep quality and in the diagnosis of sleep and respiratory-related sleep disorders. Report Studio supports manual adjudication of metadata and annotations; and calculations of basic statistical information regarding such content. The device is intended for use in a clinical environment under the supervision of a qualified clinician. | Noxturnal Web is indicated for use in the displaying, analysis and printing of pre-recorded biophysical parameters acquired during sleep for the purpose of assisting in the diagnosis of sleep and respiratory related sleep disorders.<br><br>Noxturnal Web is intended to be used as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only. | Same intended use.<br><br>Both are web-based, software only medical devices used by qualified healthcare professionals to display, review, manually score, and generate clinical reports from pre-recorded physiological sleep study recordings, with all clinical interpretation and diagnostic conclusions remaining the responsibility of the supervising clinician. |
| **Indications for Use** | Report Studio is a web-based software only medical device indicated for use in | Noxturnal Web is intended to be used for the diagnostic evaluation by a | Similar. |

| | | | |
|---|---|---|---|
| | diagnostic evaluation by qualified healthcare professionals to assess sleep quality and as an aid for the diagnosis of sleep and respiratory related disorders.<br><br>Report Studio supports the display, review, and manual scoring of physiological recordings containing cardiopulmonary, electroencephalographic (EEG), and/or other polysomnographic (PSG) signals. Report Studio supports display and user adjudication of recording metadata and annotations, can report basic statistical information regarding such content, and can aid in the generation of summary reports from user input, but does not itself independently provide automated sleep staging or similar capabilities. | physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only. Noxturnal Web is a software-only medical device to be used to analyze physiological signals and manually score sleep study results, including the staging of sleep, AHI, and detection of sleep disordered breathing events including obstructive apneas. It is intended to be used under the supervision of a clinician in a clinical environment. | Both devices are indicated for diagnostic evaluation by a physician to assess sleep quality and as an aid in the diagnosis of sleep and respiratory-related sleep disorders, with Report Studio's indication differing only in that it does not restrict the patient population to adults, a distinction addressed separately in the target patient population rationale below. |
| **Environment of Use** | Clinical environments | Clinical Environments | Same |
| **Target Users** | Medical Professionals | Medical Professionals | Same |
| **Target Patient Population** | General population | Adults | Expanded.<br><br>Report Studio does not impose an age restriction on its indicated patient population because it is a passive display and manual annotation tool whose software function is identical regardless of patient age. This |

| | | | |
|---|---|---|---|
| | | | difference does not raise questions of safety or effectiveness as the responsibility for applying age-appropriate scoring criteria rests entirely with the qualified clinician user, not the device. |
| **Type of Use** | Prescription use only | Prescription use only | Same |
| **Comparison of the Technological Characteristics** | | | |
| **Clinical Criteria:** | | | |
| **Aid/Assist in the diagnosis of sleep and respiratory related sleep disorders** | Yes | Yes | Same |
| **Arousal Scoring** | Yes | Yes | Same |
| **Respiratory Events Scoring** | Yes | Yes | Same |
| **Sleep Study Scoring Method** | Manual Scoring | Manual Scoring | Same |
| **Sleep Stage Scoring (W, N1/N2/N3, R)** | Yes | Yes | Same |
| **Report Generation** | Yes | Yes | Both subject device and predicate device automatically generate draft reports by the software but require clinician review and sign off before the report can be finalized. |

| | | | |
|---|---|---|---|
| **Calculation of AASM Standardized Indices** | Yes | Yes | Same |
| **Data Inputs:** | | | |
| EEG | Yes | Yes | Same |
| EOG | Yes | Yes | Same |
| EMG | Yes | Yes | Same |
| ECG | Yes | Yes | Same |
| Chest / Abdomen movements / Respiratory Effort | Yes | Yes | Same |
| Airflow | Yes | Yes | Same |
| Oxygen Saturation | Yes | Yes | Same |
| Body Position / Activity | Yes | Yes | Same |
| **Device Characteristics** | | | |
| **Hardware Components** | Not included | Not included | Same |
| **Software Type** | Web-based | Web-based | Same |
| **Physical Characteristics** | Web-based software operating in the cloud with Windows or Mac OS | Web-based software operating in the cloud with Windows or Mac OS | Same |
| **Other** | | | |
| **Standard of Scoring Manual** | American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events | American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events | Same |