PRESS RELEASE
11 September 2026 13:30:00 CEST

SLEEP CYCLE ACCELERATES EUROPEAN LAUNCH OF SLEEP APNEA RISK DETECTION WHILE PRESERVING PATHWAY TO US REGULATORY CLEARANCE

Class I CE marking provides an earlier route to market in Europe, enabling Sleep Cycle to establish real-world adoption and partner value while maintaining its ambition for FDA clearance in the United States and Class IIa certification in Europe.

Sleep Cycle, the leading AI-powered sleep technology company, today announced an adjusted regulatory and commercialization plan for its sleep apnea risk detection initiative. The company will complete its clinical validation study and intends to CE mark the solution as a Class I medical device under the EU Medical Device Regulation (MDR), enabling an earlier launch in the EU and the UK.

Sleep Cycle's ambition to progress toward higher regulatory classification remains, on two distinct tracks: FDA clearance in the United States, and Class IIa certification under MDR in Europe. The European Class I launch provides an opportunity to commercialize the technology earlier and establish real-world evidence around adoption, patient engagement, pricing, healthcare pathways and partner applications. These insights will help Sleep Cycle determine where, when and with which partners further investment toward Class IIa and other regulatory clearances will generate the greatest value.

The decision represents an important step in Sleep Cycle's evolution from a consumer sleep application into a broader sleep technology platform, with potential applications across digital health, regulated healthcare and life sciences.

Sleep apnea is one of the world's most common and underdiagnosed conditions. An estimated one billion people are affected, around 80 percent of them without knowing it.

Earlier commercialization, continued regulatory ambition
In the interim report for April–June 2026, Sleep Cycle reported that the US validation study had completed the planned study nights at a high recruitment rate, while internal testing continued to demonstrate strong specificity and sensitivity. The share of participants with moderate to severe sleep apnea was, however, lower than expected, meaning additional data collection would be required to provide the statistical basis for an FDA submission.

Sleep Cycle has therefore decided to take this in two stages. The first stage will complete the current clinical validation work and bring the solution to market as a Class I medical device in Europe. This enables earlier commercialization at materially lower investment and provides an opportunity to validate adoption, engagement, pricing and partner use cases in a real-world setting. The solution can initially be offered directly to consumers and through selected partners across digital health, insurance, sleep care and other healthcare services.

The second stage is the United States. Sleep Cycle intends to return to the FDA pathway once the commercial evidence from Europe is in hand, and will decide the scope, timing and investment of the additional data collection on that basis. In parallel, the company will continue to develop opportunities with life sciences, healthcare and medical technology partners in both markets, where FDA clearance or Class IIa certification could enable broader clinical applications and create additional value.

The Class I launch will therefore serve as a commercial and strategic evaluation point for the next regulatory phase. Further investment will be focused on the use cases, markets and partnerships where higher regulatory classification demonstrates the strongest potential return.

The underlying algorithm and its performance are unchanged. The revised plan changes the sequencing of commercialization and regulatory investment — not Sleep Cycle's ambition to reach the US market or to develop the technology toward broader regulated healthcare applications.

"We have built a product that works, and Class I gives us the opportunity to bring it to market sooner. Importantly, this is not a substitute for our broader regulatory ambition. It allows us to learn from real-world adoption, patient engagement and partner applications before determining where further regulatory investment creates the greatest value. The United States remains our largest opportunity — most of the people already waiting for this product are American — and we fully intend to go back to the FDA with a stronger commercial case behind us. In Europe, Class IIa is the natural next step where it enables deeper integration into healthcare and life sciences," says Mikael Kågebäck, acting CEO and CTO of Sleep Cycle.

Next steps
Work on technical documentation and the quality management system for Class I begins immediately, targeting certification and launch in the EU and the UK during the beginning of 2027.

In parallel, Sleep Cycle will continue discussions with life sciences, healthcare and medical technology partners to identify applications where higher regulatory classification can unlock additional clinical and commercial value.

Commercial traction, partner opportunities, regulatory requirements and expected return on investment will together inform the scope and timing of the next regulatory phase. The company will report on the scope, timing and expected investment of the US phase as the commercial picture develops.

For more information, please contact:

Mikael Kågebäck | Acting CEO and CTO
mikael.kageback@sleepcycle.com

Elisabeth Hedman | CFO & Head of IR
elisabeth.hedman@sleepcycle.com | +46 76 282 8958

About Sleep Cycle
Sleep Cycle is dedicated to making healthy sleep accessible to everyone. Our app helps users to build hero habits, identify potential sleep issues, and gain valuable insights into their sleep patterns. Leveraging patented sound technology and over 4 billion analyzed sleep sessions, Sleep Cycle provides great accuracy and personalized guidance. As part of its broader partnership program, Sleep Cycle offers company partnerships including in-app promotions, tailored SDK solutions, and an extensive data library, enabling businesses to expand their offerings with sleep solutions and insights. Sleep Cycle is listed on Nasdaq Stockholm under the ticker SLEEP, with its headquarters in Gothenburg, Sweden.