

# FDA Approves New Device for Insomnia

Pauline Anderson | June 08, 2016

The Cerêve Sleep System, a prescription device that helps reduce latency to stage 1 and stage 2 sleep by keeping the forehead cool has received US Food and Drug Administration (FDA) commercial clearance for use in patients with insomnia, the company has announced.

The inspiration behind the new device came from functional brain imaging studies conducted by Eric Nofzinger, MD, a board-certified sleep physician and founder of Cerêve, at the University of Pittsburgh in Pennsylvania, the company notes in a press release. These studies confirmed that in patients with insomnia, the frontal cortex stays active, preventing them from getting deeper, more restorative sleep. These patients often describe a "racing mind" that interferes with getting a sound sleep.

Dr Nofzinger found that gently cooling the forehead within a precise, clinically proven therapeutic range reduced this activity in the frontal cortex. The new software-controlled bedside device cools and pumps fluid to a forehead pad that is worn throughout the night.

## Clinical Studies

Three clinical studies that included more than 230 patients over 3800 research nights demonstrated the safety and efficacy of the device. In one of these — a randomized, placebo-controlled trial of people with primary insomnia at seven clinical sites across the United States — results from polysomnographic sleep measurements showed a statistically significant reduction in latency to stage 1 sleep, the time taken to get into the first stage of sleep, as well as latency to stage 2 sleep.

Across two additional studies, self-reports from patients demonstrated that the quality of their sleep improved over 30 days of in-home use of the Cerêve Sleep System.

The FDA evaluated the company's application under a de novo classification for novel, low-risk devices. Clinical studies over 3800 nights confirmed this low-risk safety profile.

The new system is expected to be launched during the second half of 2017, said Craig Reynolds, president and chief executive officer of Cerêve.

According to background provided by the company, about 55 million Americans have insomnia, experiencing not only problems getting to sleep but also serious impairment in their daytime activities. The cost of insomnia is over \$100 billion annually in the United States, which includes costs related to poorer workplace performance, increased healthcare utilization, and increased accident risk.

Sleeping pills have by far been the most common medical treatment, with nearly 9 million adults having taken prescription sleeping pills in the last 30 days, according to the press release. But this comes with well-established safety risks, including decreased mental alertness the morning after use.

These medications can cause next-day impairment of driving and other activities that require full alertness, leading physicians and patients to seek a drug-free alternative, the company notes.

"This is the first and only insomnia device cleared to reduce sleep latency to stage 1, the first stage of sleep, as well as stage 2, a stage of sleep that typically represents over 50% of the sleep period," Dr Nofzinger said in the company statement. "The Cerêve System offers a clinically proven and safe alternative to pills, with the potential to help millions of Americans get to sleep fast."

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