Health Technology Review	
Technology Ref.:	HTA23021
Technology Name:	Modius Sleep
Approvals by International Bodies:	FDA 510(k) clearance pending (Reference K230826).
Company name:	Neurovalens Limited
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Short Description of the Technology:	Modius Sleep is a low-risk, non-invasive neurostimulation device which consists of a batterypowered headset designed to transcutaneously deliver low-level electrical energy (neurostimulation) to the vestibular nerves in a way that can be used to treat insomnia. The Modius Sleep device utilizes Electrical Vestibular Nerve Stimulation (VeNS) as its operating principle to influence the suprachiasmatic nucleus (SCN) of the hypothalamus, an area that controls the circadian rhythm and sleep patterns.

Health Technology Assessment Team Recommendation:	**Disapprove**

Summary of Review:

Modius SLEEP is a headset worn just behind the ears. It sends a low-level electrical signal to the part of the brain that controls sleep, the hypothalamus. The company claims this signal helps to rebalance the user's sleep system, allowing for a more restful sleep and assisting those struggling with insomnia, sleep deprivation, and other sleep disorders.

Advantages	Disadvantages
Non-pharmaceutical approach: Modius Sleep provides a drug-free alternative to traditional sleeping aids, which can be beneficial for those who are concerned about potential side effects or dependencies associated with some medications.	Absent of international bodies approval
Ease of use: The device is generally easy to use. Users simply put it on for a period of time before they plan to go to sleep	Limited definitive scientific evidence supporting the effectiveness of Modius Sleep
Potential improvements: Some users have reported improvements in sleep quality, duration, and ease of falling asleep. However, individual results may vary	Some users have reported minor side effects, such as skin irritation at the electrode site, headaches, or dizziness

We recommend a **disapproval of using this technology** for clinical practice at the current time as further research and validation are necessary to fully comprehend the implications and limitations of this technology, ensuring its successful integration into clinical practice.

Technology Image