

Category

Best Startup

Product/Solution Name

MindMics Heart Health System

Date of Approval

N/A

Indications

MindMics is embarking on its commercialization journey by offering well-being solutions that leverage clinically validated heart rate and heart rate variability data. In our initial product release, our focus is not on diagnoses, which means we do not require FDA clearance at this stage. However, we are actively engaged in comprehensive research and development efforts to expand our system capabilities by incorporating essential hemodynamic metrics such as blood pressure. We are diligently working towards meeting the necessary requirements and paving the way to obtain FDA clearance in the future.

Therapeutic Categories

MindMics is dedicated to supporting individuals who have experienced major health events, such as heart attacks, in their journey towards regaining control over their well-being. We recognize the challenges faced during recovery, which is why we offer a robust heart health system that equips users with practical and effective tools. By placing emphasis on stress recovery and blood pressure management, our solutions are tailored to meet individual needs, providing actionable steps for users to actively manage their health and thrive.

Attached Files:

- MindMics Product Brochure2.pdf
- MindMics Product Brochure2.pdf
- MindMics Product Brochure 1.pdf

Background information and need for solution/product

The MindMics Heart Health System is an innovative and comprehensive solution specifically designed to address the growing need for next-generation heart health monitoring. Our system combines clinical accuracy with ease of use, seamlessly incorporating into everyday life. At the core of our technology is the patented in-ear Infrasonic Hemodynography, which enables heart health monitoring through everyday earbuds.

Heart disease remains a leading global cause of death, affecting millions of individuals with various cardiovascular conditions. Timely detection, continuous monitoring, and effective management are vital for preventing complications and improving overall cardiac health. Moreover, the financial strain of readmissions poses significant challenges for hospitals and healthcare systems. Factors such as stress, anxiety, and uncontrolled high blood pressure contribute to readmissions and further cardiac

complications.

At MindMics, we are dedicated to supporting individuals who have experienced major health events, such as heart attacks, and empowering them to regain control over their well-being. Our heart health system offers a comprehensive set of tools and resources tailored to individual needs. We focus on stress recovery and blood pressure management, which are critical factors in maintaining heart health. By providing actionable steps, we enable users to actively manage their health and thrive.

Today, MindMics combines sound data with insights and guidance to help people improve their health. We collaborate with leaders across industries to make this sound technology accessible to more individuals. Our vision is to create a GPS for health and well-being, delivering real-time, accurate health data and an actionable user experience that influences behavior and drives better health outcomes. Our platform already generates revenue through infrasonic lab services and licensing heart rate algorithms to premium earbud brands, scheduled to be available on the market in Q4 2023.

However, our journey does not stop there. We are committed to rigorous clinical studies with leading centers and ongoing R&D to expand our offering in the near future. This includes monitoring key hemodynamic metrics like blood pressure and potentially developing screening tools to detect signs of major cardiovascular diseases. Our ultimate goal is to provide people with actionable data that eliminates heart failure as the leading cause of death globally, similar to how glucose monitoring revolutionized diabetes management.

In summary, the MindMics Heart Health System, already available for presale, addresses the pressing need for advanced heart health monitoring and management. By focusing on stress recovery, blood pressure management, and personalized tools, we empower patients to take an active role in their cardiac health. Through our innovative approach, we aim to improve patient outcomes, enhance quality of life, and alleviate the burden on healthcare systems.

MindMics is thrilled to participate in the Technology's Golden Age series – presented by the Consumer Technology Association and produced by BBC StoryWorks – which explores the critical themes of “tech for good” and “long lives well-lived.” Watch our video to learn how MindMics is helping our members live healthier lives: <https://www.mindmics.com/healthier-lives>

History of the development of the solution/product

MindMics Founder & CEO, Dr. Anna Barnacka, a former NASA Einstein Fellow at Harvard University studying black holes with precision instruments, recognized a glaring gap in the market—there were no tools available to help her understand her own health. Existing options were either cumbersome and impractical or unreliable and imprecise.

Driven by this realization, Dr. Barnacka embarked on a quest to develop a new way of monitoring health that would be as effortless as listening to music yet as accurate as medical devices. Through analyzing low-frequency acoustical vibrations detected in the ear canal, she successfully captured subtle sound variations that painted a precise picture of her health. This groundbreaking discovery

marked the beginning of a health monitoring revolution.

In 2018, Dr. Barnacka founded MindMics, aiming to create a next-generation health monitoring platform using this groundbreaking sound-based technology, known as infrasonic hemodynography (IH), integrated into everyday earbuds.

Recognizing the wealth of information embedded within each heartbeat detected by MindMics, and supported by a stellar team of cardiologists, MindMics embarked on a rigorous path from the outset to validate its technology and explore its potential to revolutionize the measurement and diagnosis of key cardiac conditions such as atrial fibrillation, aortic stenosis, and pulmonary hypertension, among others.

MindMics' sound-based technology™ has undergone rigorous clinical validation in collaboration with leading researchers and renowned medical institutions. A clinical study conducted in collaboration with Prisma Health demonstrated that MindMics can measure the time between heartbeats with an accuracy equivalent to the gold standard ECG, even for complex heartbeats like those in atrial fibrillation. In fact, MindMics has achieved a remarkable 99% accuracy in measuring heart rate and heart rate variability compared to ECG, eliminating the need for expensive and inconvenient ECG tests. Another study conducted by Scripps Health using MindMics technology revealed insights into hemodynamics, shedding light on how blood flows through blood vessels, which would not have been possible with an ECG alone. Principal investigator Dr. Sanjeev Bhavnani stated, "MindMics technology shows a high correlation with medical-grade standards like echocardiogram and cardiac catheter." These clinical studies demonstrate MindMics' potential to detect valvular diseases without the need for invasive and costly methods. Additionally, we have successfully identified hemodynamic features characteristic of severe aortic stenosis and heart murmurs. This is just the beginning of our journey as MindMics continues to collect data and push the boundaries of health monitoring.

The groundbreaking advancements achieved by MindMics highlight the transformative impact our technology can have on cardiac health. We remain committed to further research, development, and data collection as we strive to revolutionize the field of health monitoring and improve everyone's health outcomes.

Why this solution/product is innovative, the broad implications for future research, and/or how it will improve the human condition

MindMics, the pioneering force behind in-ear infrasonic hemodynography (IH), is leading a revolutionary movement by capturing unique Human Audiom Data that has the potential to transform healthcare delivery through smartphones and their accessories, such as earbuds and hearing aids. It's worth noting that earbuds alone hold three times the market share of smartwatches, with an estimated 750 million truly wireless earbuds set to be shipped worldwide in 2024!

Why sound triumphs over light:

Most wearables available today utilize photoplethysmography (PPG) light technology for measuring heart rate and other key biometrics. However, PPG readings, whether from wrist or finger sensors, only scratch the surface of the skin. Factors like skin tone, thickness, perspiration, and body mass significantly impact the accuracy of PPG-based wearables, rendering them inadequate for many

individuals. MindMics, on the other hand, leverages its patented infrasonic technology to monitor crucial organs like the heart through low-frequency acoustical vibrations detected in the ear canal. This revolutionary technology, embedded in earbuds and hearing aids, surpasses the limitations of PPG light technology in numerous ways.

Exploring In-ear Infrasonic Hemodynography (IH):

Bodily mechanisms and functions generate low-frequency sounds that provide valuable insights into cardiovascular health, despite being inaudible to humans. MindMics has invented and patented In-ear infrasonic hemodynography (IH), a technology capable of measuring these low-frequency sounds produced by vital organs, thus empowering powerful, next-generation health monitoring systems. IH accurately delivers biometric data like Heart Rate (HR) and Heart Rate Variability (HRV) with a remarkable 99% correlation to an ECG. In fact, IH goes beyond an ECG by offering a comprehensive view of every heartbeat and shedding light on associated hemodynamics—the flow of blood through blood vessels. In the future, IH holds the potential to detect hazardous heart rhythms, including Atrial Fibrillation (AF), even in asymptomatic cases, thereby saving countless lives.

To establish measurement standards and fine-tune the performance of our system within the infrasound range, we have developed cutting-edge laboratories. Our unwavering focus lies in delivering next-generation health monitoring technology, clinically validated in world-leading centers. The MindMics team thrives on conquering challenges that others may perceive as insurmountable, continuously pushing the boundaries of what is deemed possible. Through this pursuit, we enhance our understanding of our own bodies, unlock new frontiers in healthcare, and enable advanced health monitoring capabilities today.

The MindMics journey exemplifies audacious determination, bringing together expertise from diverse fields to create a groundbreaking system capable of capturing and deciphering the symphony within our bodies, in ways that were once unimaginable. Our passion for innovation and relentless pursuit of knowledge merge as we forge a path toward a future where our internal vibrations can be harnessed effortlessly, optimizing our health and well-being—just as easily as listening to music through a pair of beloved earbuds.

Please provide appropriate references (ie Pubmed links)

1. Shen CP, Wheeler C, Waldman CE, et al. Can a novel earbud detect aortic stenosis murmur before and after transcatheter aortic valve replacement? *_Journal of the American College of Cardiology_*. 2023;81(8_Supplement):2233-2233. doi:[10.1016/S0735-1097(23)02677-3]([https://doi.org/10.1016/S0735-1097\(23\)02677-3](https://doi.org/10.1016/S0735-1097(23)02677-3))
2. Gilliam FR, Ciesielski R, Shahinyan K, et al. In-ear infrasonic hemodynography with a digital health device for cardiovascular monitoring using the human audiome. *_npj Digit Med_*. 2022;5(1):1-13. doi:[10.1038/s41746-022-00725-3] (<https://doi.org/10.1038/s41746-022-00725-3>)
3. Waldman CE, Patel S, Wheeler CM, et al. Abstract 13654: Can a Novel Earbud Technology Detect Severe Aortic Stenosis? Modernizing the Wiggers Diagram Through Infrasonic Hemodynography Synchronized With Echocardiography and Cardiac Catheterization. *_Circulation_*. 2021;144(Suppl_1):A13654-A13654. doi:[10.1161/circ.144.suppl_1.13654] (https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.13654)

4. Wheeler CM, Patel S, Waldman CE, et al. Abstract 11669: "Hearing the Heart" - Validation of a Novel Digital Health Earbud Technology to Measure Cardiac Time Intervals Through Infrasonic Hemodynography. *_Circulation_*. 2021;144(Suppl_1):A11669-A11669. doi:[10.1161/circ.144.suppl_1.11669] (https://doi.org/10.1161/circ.144.suppl_1.11669)
5. Gilliam FR, Shahinyan K, Panchal J, et al. B-AB24-01 MINDMICS: IN-EAR INFRASONIC HEMODYNOGRAPHY FOR CARDIAC ARRHYTHMIA ASSESSMENT BEYOND ECG. *_Heart Rhythm_*. 2021;18(8):S46. doi:[10.1016/j.hrthm.2021.06.134] (<https://doi.org/10.1016/j.hrthm.2021.06.134>)