



Soundwave Hearing, LLC Announces 510k FDA Clearance for Sontro® Self-Fitting OTC Hearing Aids and the AI award-winning otoTune® app.

Oak Brook, IL, November 6, 2023 - [Soundwave Hearing](#) today announced 510k FDA clearance for its Class II Medical Device, Sontro® Self-Fitting OTC Hearing Aids, opening the door for Americans to access affordable hearing aids. By combining the power of mobile phones and unique self-fitting AI technology, Soundwave Hearing has created custom personalization for its Sontro Self-Fitting OTC Hearing Aids, removing common barriers to accessing hearing aids.

A recent study in [The Lancet](#) highlights hearing loss as the top modifiable risk for cognitive decline in older adults. Despite 37.5 million Americans facing hearing challenges, 80% who could benefit don't use hearing aids. Over-the-counter (OTC) hearing aids offer a promising and affordable solution, aiming to make hearing health accessible for all.

"The 510k FDA Clearance for the Sontro Self-Fitting OTC Hearing Aids is particularly timely, given the regulations for OTC hearing aids and the growing demand for telemedicine-based services. We are extremely proud of our ability to create a personalized, self-fitting OTC hearing aid, a true milestone. It's a leap forward in making hearing healthcare more accessible, patient-friendly, and ensuring a brighter cognitive future for many." said Anthony Florek, President, Co-Founder of [Soundwave Hearing](#).

What Makes the Sontro Self-Fitting OTC Hearing Aids Different than other Self-Fitting OTC Hearing Aids?

Personalized Self-Fit: Uniquely, using revolutionary AI technology, Soundwave Hearing has developed a method for users to self-fit their personal hearing needs. Soundwave does not use predetermined settings. Every device is programmed to each user's specific hearing requirements.

- How Does Soundwave Achieve Personalized Self-Fit?
 - The Sontro Self-Fitting OTC Hearing Aids, and otoTune® app use a 3-minute in situ hearing test to customize the self-fitting process (in situ: a hearing test is administered while wearing the devices, paired to the app).
 - The patented otoTune app tests both ears simultaneously using the devices, delivering clinically validated test results and programming to the user's unique hearing and listening needs.

Unique State-of-the-Art Customization: Sontro OTC Self-Fitting Hearing Aids are the first self-fitting OTC hearing aids on the market to offer Automatic Mode Selection and Adaptive Directionality.

- Why does this matter?
 - Automatic Mode selection intelligently monitors the environment and automatically selects the most appropriate sound mode to help the user hear their best in every listening situation, allowing them to move more seamlessly from quiet to noisy listening situations.
 - Adaptive Directionality allows the user to follow a conversation easily by using directional microphones to better identify speech in noisy environments (restaurants).



Aural Rehabilitation: Soundwave Hearing's partnership with Amptify DTx has the consumer's hearing health in focus; it is one of the first OTC hearing aids to offer Aural Rehabilitation with the purchase of an OTC hearing aid. Providing a hearing health coach, listening games, an interactive curriculum, and a support community. [Learn More](#)

Soundwave's Published Research: A collaborative research study with top institutions, establishing that a patient-controlled hearing assessment with a hearing aid in a non-clinical setting is statistically comparable to an audiologist-controlled hearing assessment in a clinical environment. Central to the study was Soundwave's award-winning otoTune® app, which was used to perform patient-controlled hearing assessments in the study.

- Resonance Medical, LLC and Soundwave Hearing, LLC provided funding for the research.
- The article has been published in Scientific Report, a respected and widely-read scientific journal. [Link to Study](#)

OTC Hearing Aid Features: The Sontro Self-Fitting OTC Hearing Aids connect via Bluetooth® to the otoTune® app. Technology includes receiver in the canal (RIC) design, 16-channel wide dynamic range compression, noise reduction and feedback cancellation, automatic mode selection, and adaptive directionality. Users can also effortlessly adjust volume, frequency tones, and listening modes. They come with a 45-day Risk-Free guarantee, 1-year warranty, and lifetime customer support. The hearing aids are eligible for FSA and HSA reimbursement. The otoTune technology is available on iOS and Android.

The devices are adjusted by the user, and no preprogramming or hearing test is necessary. They are intended for over-the-counter (OTC) sale and use without a hearing care professional and will be offered for **\$749/set**. Self-fitting OTC hearing aids have been developed to amplify sound for individuals 18 years or older with perceived mild to moderate hearing impairment.

About

[Soundwave Hearing, LLC](#) is a health tech company passionately committed to the idea that good hearing health improves lives and believes that everyone should have access to high-quality hearing technology without the barriers associated with conventional hearing aids.

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Link to images:

[otoTune® app control screen](#)

Beige and Grey Sontro Self-Fitting OTC Hearing Aids: [Beige](#) & [Grey](#)