

## FDA Gives Approval for Over-The-Counter Home Hearing Test

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*SAN LEANDRO, CALIFORNIA* — Over the past year, there has been growing interest in the morphing of consumer electronics and medical devices. New product categories are [being created](#) and the hearing care industry seems to be on the brink of some significant changes, especially in light of the recent non-binding [PCAST recommendations](#) to re-regulate the hearing aid marketplace.

A recent [press release](#) from iHear Medical of San Leandro, California, indicates that these disruptive forces are not confined to consumer devices, as the company announced on January 4th it has obtained FDA clearance for the [iHearTest™](#). It is being billed as the world's first hearing screener approved for over-the-counter (OTC) sales.

### Targeting Those Reluctant to Seek Professional Help

According to the press release, the iHearTest is a hearing screener for profiling hearing ability based on the World Health Organization (WHO) guidelines, targeting adults who suspect they have hearing loss, or those reluctant to seek professional evaluation for a basic hearing assessment.

The iHearTest and other hearing solutions developed by iHear Medical seem to be in-line with PCAST recommendations, calling for more affordable and accessible services with age-related, progressive, mild-to-moderate hearing loss.

“The iHearTest is a disruptive new technology and cost saving method that can expand hearing care significantly. Less than 1/3 of physicians include hearing screening for their patients and millions in the mild to moderate hearing loss range go untreated, which increases their risk of dementia along with losing friendships, jobs and careers. iHear's breakthrough home hearing test is a game-changer for millions of consumers seeking affordable and accessible hearing solutions” stated Randy Pozos, PhD, president and healthcare technology analyst with Advanced Knowledge Resources, Inc

The iHear Medical press release goes on to say that the FDA approval of the iHearTest was based on extensive technological development and clinical research to demonstrate safety and efficacy, as an Institutional Review Board (IRB)-approved clinical study was conducted on 96 subjects with iHearTest results compared to WHO grading of hearing impairment using standard practice audiometry.

The clinical study results showed 96.4% agreement with the WHO method using standard practice audiometry for the assessment of disabling hearing impairment. For the ordinal assessment of hearing ability, the iHearTest showed 85.9% level-by-level agreement and 100% agreement within

±1 level with respect to WHO grading using standard practice instruments.

## Touted for its Ease of Use and Secured Access

The iHearTest kit includes a handheld USB device for connection to a personal computer and factory-calibrated earphones. The iHearTest software application is downloaded online and provides step-by-step instructions on how to administer the iHearTest. The iHearTest kit requires a standard personal computer running Microsoft Windows or Mac OS X.

### Included in the iHearTest



- (1) iHearUSB Device
- (1) Calibrated Earphone
- 2x Assorted Ear Tips Set (S, M, L)
- Quick Install Guide
- User Guide

Test results are stored on a remote HIPAA-compliant server for review any time by the consumer using secure online access. The iHearTest system also conducts periodic checks of earphone calibration to ensure continued test signal accuracy. The iHearTest is not intended as a diagnostic test to evaluate hearing health or treat ear disease. The test advises consumers to seek professional evaluation for any symptoms that may indicate a health issue.

As many hearing care professional can attest, the delay in basic assessment of hearing loss presents challenges for the hearing health system, which often deals with hearing loss at the severe stages, rather than early on during the mild and moderate stages. Further, psychological and other barriers prevent many from seeking professional evaluation early on, resulting in untreated loss and communication barriers.

The lack of solutions available directly to consumers or through their primary care providers results in a delay in basic hearing assessment and treatment of about 6-9 years according to industry reports.

## Future Pricing and Plans

iHear Medical plans to retail the iHearTest kit for \$49 USD which includes testing for two family members. The iHearTest is protected by four U.S. and international patent applications. Readers can learn more by visiting the [iHearTest site](#).

iHear Medical plans to offer a range of innovative web-based hearing solutions directly to consumers and through partnerships with leading insurance and professional distribution channels. Recently, the company announced partnerships with [Ameritas](#), a major U.S. insurance provider,

and AIER