

## US clearance of Bose hearing aid is just the start



[Elizabeth Cairns](#)



### **The market clearance of the US's first do-it-yourself hearing aid has knocked the traditional groups, but the real battle commences in 2020.**

The age of the over-the-counter hearing aid is... not quite here. But the FDA has taken a step towards it, with *de novo* clearance of the first hearing aid patients can fit and adjust without the intervention of an audiologist. Users can tweak the settings of the Bose Hearing Aid using a phone app, but they will still need a prescription to get one.

Even so, the FDA's decision has had a sobering effect on investors in traditional hearing aid developers. The three big listed groups, William Demant, Sonova and GN Store Nord, were down 11%, 10% and 8% respectively at yesterday's close.

Full clinical data on the Bose device are not available, and without these it is hard to make any efficacy comparison with competitors. But how much of a threat this new market entrant poses to the groups now occupying the space might be determined less by efficacy than by price.

Current hearing aids go for upwards of \$1,000 and are not routinely covered by Medicare or private insurance. Only a small part of that cost is the device - the remainder goes towards testing the patients' hearing and choosing, programming and adjusting the system ([Over the counter hearing aids could shake up an industry, December 15, 2016](#)). With most of these steps unnecessary with Bose's hearing aid it could be sold more cheaply, luring customers away from the traditional model.

The real reckoning, though, will come in 2020. This is when the FDA is scheduled to introduce new regulations permitting the sale of hearing aids that are truly over-the-counter, with patients no longer being required to get their hearing tested or to get a prescription before buying one.

The new regulations are still being drafted so it is not clear yet what provisions they will contain. However it seems increasingly likely that they would permit the sale, either in store or online, of 510(k)-cleared hearing aids that have met basic safety and performance standards, to adults with "perceived mild-to-moderate hearing impairment" - in other words, anyone who wants one.

### **Big five**

This will likely encourage more new entrants into the market, the lion's share of which is currently occupied by six manufacturers - Sonova, William Demant, GN Store Nord, Sivantos, Starkey and Widex. This list will soon shrink: Widex's takeover of Sivantos has not yet closed ([Sivantos-Widex allows EQT to reset the clock, May 16, 2018](#)).

The FDA said it had based clearance of the Bose device on clinical research in 125 patients, and this found that users adjusting the device themselves had “comparable ... outcomes” to patients who had the same product fitted and programmed by professionals with respect to selected level of amplification, speech in noise testing and overall benefit. Patients who self-fit the Bose Hearing Aid generally preferred the settings they chose over the professionally selected settings.

There is no record for the Bose Hearing Aid on [clinicaltrials.gov](https://clinicaltrials.gov), and the labelling for the product is not yet available on the FDA’s website. As no further details are yet available it is hard to make efficacy comparisons. Inter-device comparisons on the metric of picking out speech in a noisy environment might be particularly interesting given Bose’s expertise in noise-cancelling.

It will take considerable marketing heft to cut in here. But high-end consumer electronics brands like Bose have exactly this kind of heft, and could appeal to the same customers who currently buy their speakers and headphones – people for whom sound quality is paramount.

In the event that there is notable competition to the established leaders, Bernstein analysts write that William Demant is most exposed, followed by Sonova and GN Store Nord. Demant and Sonova own retail stores, and thus would face serious profit headwinds if the stores came under financial pressure. GN’s shops, however, are franchises and the company only books the wholesale price of its hearing aids.

If Bose is the only high-end consumer audio brand to branch into hearing aids the current rulers will not be affected too badly. But both Apple and Google’s parent Alphabet have been pursuing healthcare avidly, albeit in different areas. If they choose to follow Bose into hearing aids – something the new regulations could make more appealing – the established groups could face a major challenge.