

**Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue
Washington, DC 20580**

DATE
2017-05-17

**RE: NOW HEAR THIS - Competition, Innovation, and Consumer Protection
Issues in Hearing Health Care, follow up workshop**

Dear FTC Commissioners and Staff:

Two Pi GmbH is a Europe-based supplier of technology for hearing healthcare industry. Since 2003 we have been providing known hearing aid manufacturers with signal processing intellectual property and firmware for DSP and Bluetooth-based products.

We are pleased that the FTC invites the public to participate in the OTC discussion and would like to bring our opinion and experience to the discourse:

Two Pi sees the improvement of US hearing healthcare explicitly as technology driven improvement. As in other medical branches, innovation is no longer only related to the hearing instrument itself, but increasingly to the regulation and utilization of novel health maintenance processes in app form. A shift in delivery of audiology services from current procedures to automated app procedures makes sense!

It is important to note that the OTC model can be a shift in technology, and not only a new mechanism for delivering the product.

This statement is based on our experience in the R & D project for user-driven fitting of hearing aids, carried out together with the Academic Medical Center, Department for Clinical and Experimental Audiology (AMC), Amsterdam. The app has been validated on test subjects within the clinical pilot study at AMC and went through the FDA pre-sub 510(k) under ref. number Q130955 in 2013.

The technology can be either used as an economic alternative for prescription based tele audiology supplies or as a full OTC supply. As a counseling feature it starts after the conventionally achieved first fit. Formally the feature is a translation of paired comparison hearing aid adjustment (fine-tuning) into an interactive procedure.

As a full OTC supply the app combines hearing loss screening for people with a sensorineural mild to moderate hearing loss up to 60 dB and additional interactive paired comparison.

However, in spite of mature underlying technology and proven safety and efficacy, this technology is not embraced by the industry. In our opinion, the apparent reason is that this step would represent a substantial innovation and would not match current vertically integrated hearing healthcare provisioning.

While altering the range and quality of hearing healthcare, the novel user-driven technology would have its impacts on the existing hearing aid products and audiology service supplies.

Now, 2Pi and the AMC would like again to attempt presenting the novel app technology and give contribution to the current OTC discussion. From the very beginning we have been designing an automated, user-driven app procedure that is modular designed and can either partially or fully replace the standard audiology services. The results of the clinical study deliver evidence that a technology-driven improvement of hearing healthcare is feasible.

If you would like to receive any additional information or material on the prototyped app, please contact Ernestine Bennersdorfer (ebenners@two-pi.com), responsible for business development at Two Pi

Sincerely,
Tarik Zukic
Managing director Two Pi GmbH

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