

OTC Hearing Aids: One Year Later

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***“The One Most Adaptable to
Change is the One that Survives”***

- Charles Darwin

Goals of the OTC Regulation

Accessibility



Affordability



Innovation



Goal 1: **Accessibility**

- We now have over 40 companies selling OTC devices
- Over 80 have filed registrations or an application with the FDA



Where OTC's Will Be Sold



Hearing Care Professionals – may dispense both OTC and prescription devices

Retail Stores – offer several models at various price points



Pharmacies – offer several models at various price points



Online

Examples of OTC Offerings



Eargo
Go Prime
HP Hearing
Jabra
Lexie
Lucid
Sennheiser
SONY
Williams Pocketalker



Go Hearing
Hearing Assist
HP Hearing
iHEAR
Lexie
Lucid
Rx Ears



Hearing Assist
Lexie

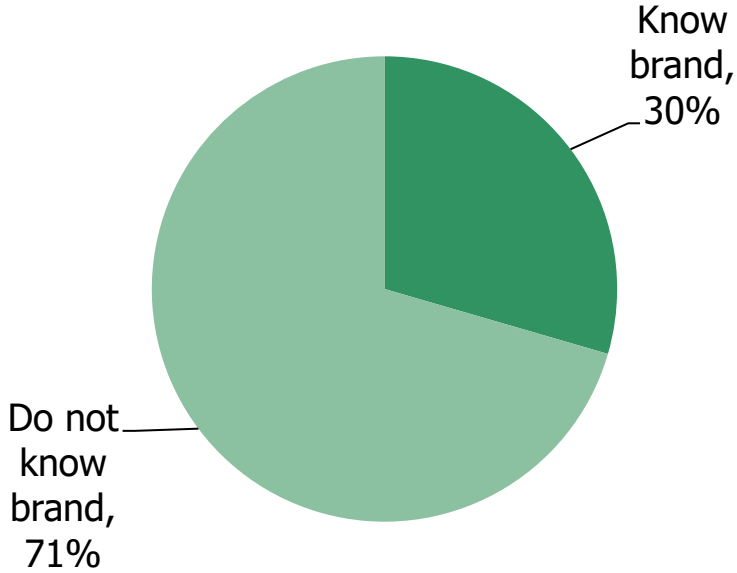


Eargo

The Value of Brand Partnerships

Awareness of Brand of Current Hearing Aid*

(Current HA Owners (n=1139))



*MarkeTrak22



Two Recent Surveys of Hearing Professionals

Hearing Tracker Survey

HCPs who will support patients that purchase OTC devices elsewhere: **55%**

HCPs who plan to sell OTC devices: **26%**

HCPs who will not sell or service OTC devices: **19%**

I currently dispense hearing aids	85%
I will support patients with OTC hearing aids purchased elsewhere	55%
I will sell OTC hearing aids in my clinic or on my website	27%
I will offer unbundled prices to compete with OTC hearing aid price	42%
I employ best practices or plan to improve my standard	87%

*V. Manchaiah, JAAA, 2023

Goal 2:

Affordability



Less Than \$400

Audien	\$99 to 249.00
Auditech	\$249.00
Bluids	\$299.00
Bossa	\$89.97
Ceretone	\$349.00
Chosgohearing	Various
Fisdemo	\$369.00
Go Hearing	\$169-\$299
Hammacher Schlemmer	\$349.95
Hexo	\$149.99
Linner (buds)	\$299.00
Lizn (earphones)	\$199.00
MDHearing	\$297.00
Melofair	\$230.00
Neosonic Hearing Aid	\$349.00
Nuheara	\$249.00
Ober Hearing Aid	\$129.99
Panda hearing	\$249.00
Sensley SO1 (VIVTONE)	\$89.97
Smart Hearing Aid	\$199-\$299

Greater than \$400 and Less Than \$1000

Acosound	\$689.00
Bluids	\$999.00
Ear Technology	\$699.00
Embrace hearing	\$899.00
Hearing Assist	\$599.00
HP	\$499.00
Innerscope	\$999.00
Jabra enhance (buds)	\$799.00
Lexie	\$899.00
MD Hearing	\$999.00
NANO (at home)	\$697.00
Nuheara	\$499.00
Sony (WSA)	\$999.00
Soundwave	\$849.00
Soundwise	\$499.00
ZVOX	\$599.00

Over \$1000

Olive Union	\$ 1,059.00
Jabra	\$ 1,195.00
Sennheiser	\$ 1,499.00
ORKA	\$ 1,899.00
eargo	\$ 2,550.00
Audicus	\$ 2,798.00
America Hears	\$ 3,799.00
Bluemoth	\$ 5,500.00

Pricing

2022 HIA Omnibus Survey*



Q13. If you had to estimate, how much would you be willing to pay for the highest quality and most effective set of hearing aids available on the market?

	Total
Less than \$499	22%
\$500 to \$999	20%
\$1000 to \$1999	18%
\$2000 to \$3999	13%
\$4000 to \$4999	7%
\$5000 or more	5%
Not Sure	15%

*Dec. 2022 - APCO

How Will Insurance Companies View OTC

Insurance

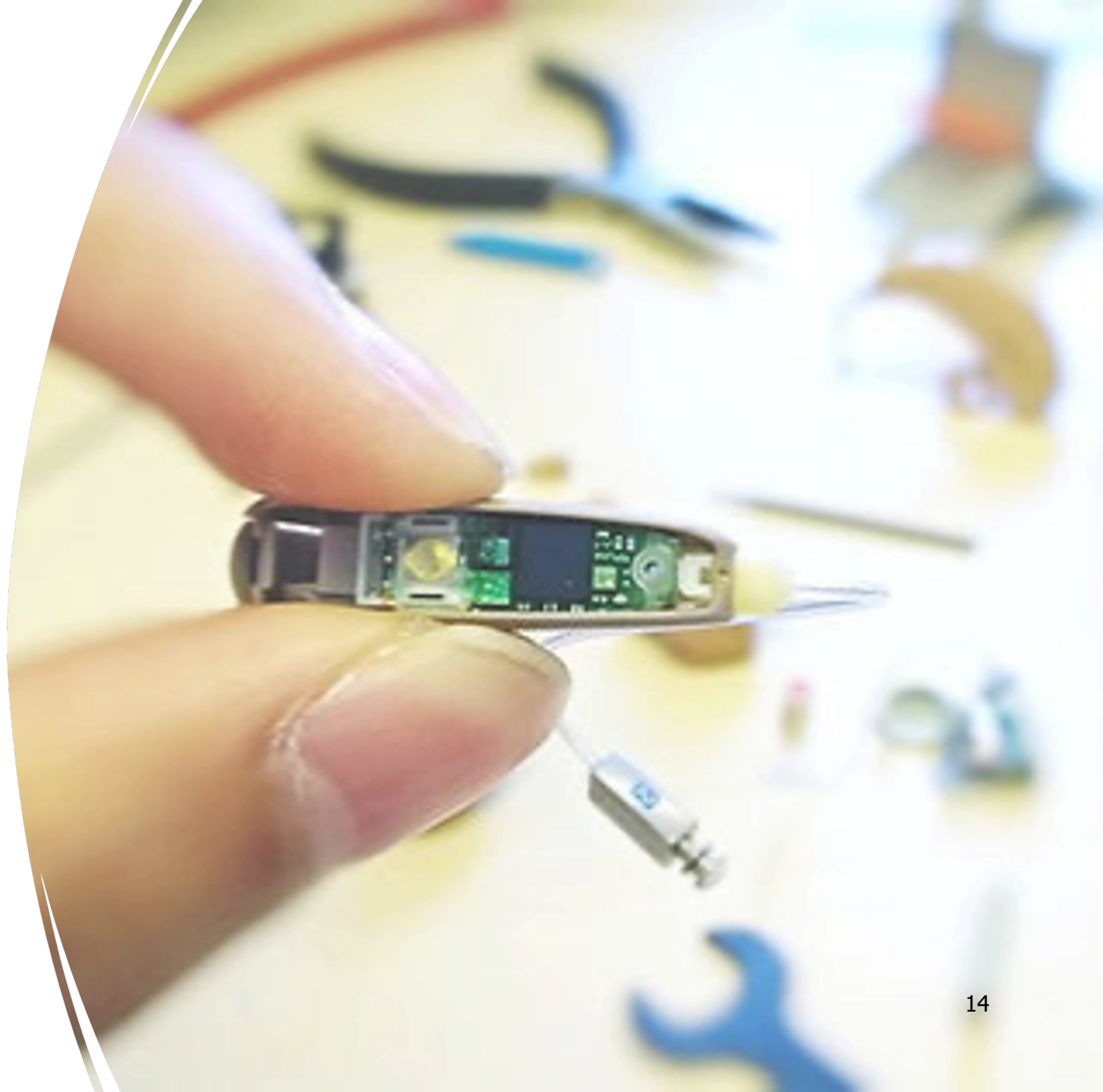
- Will insurance cover both prescription and OTC devices, OR will they only pay for OTC products?
- Will the patient receive a “bonus” if they buy OTC?

Traditional VS. Medicare Advantage

- Traditional Medicare does not cover hearing aids
- Medicare Advantage Plans offer hearing health benefits at various levels

Goal 3:

Innovation



Innovation

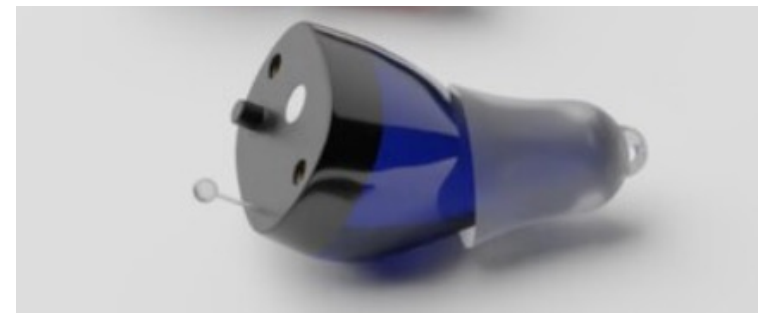
The signal processing features found in OTC devices already exist in Rx devices:

- ✓ Directional microphones
- ✓ Feedback reduction
- ✓ Noise suppression
- ✓ Rechargeable batteries
- ✓ Wireless connectivity





Existing Form Factors





New Form Factors





Self Fitting Devices*



QUH – Self-fit OTC to be sold online and retail locations

- Eargo 7, 6
- GN Enhance
- hearX Lexie B1 & B2
- hearX Lexie Lumen
- MD Hearing Volt Max 2
- MD Hearing CORE
- Novidan NoviONE
- Nuheara
- Sonova All Day Clear ADC1 and ADCS1



QDD – Self fit to be sold online – Not OTC

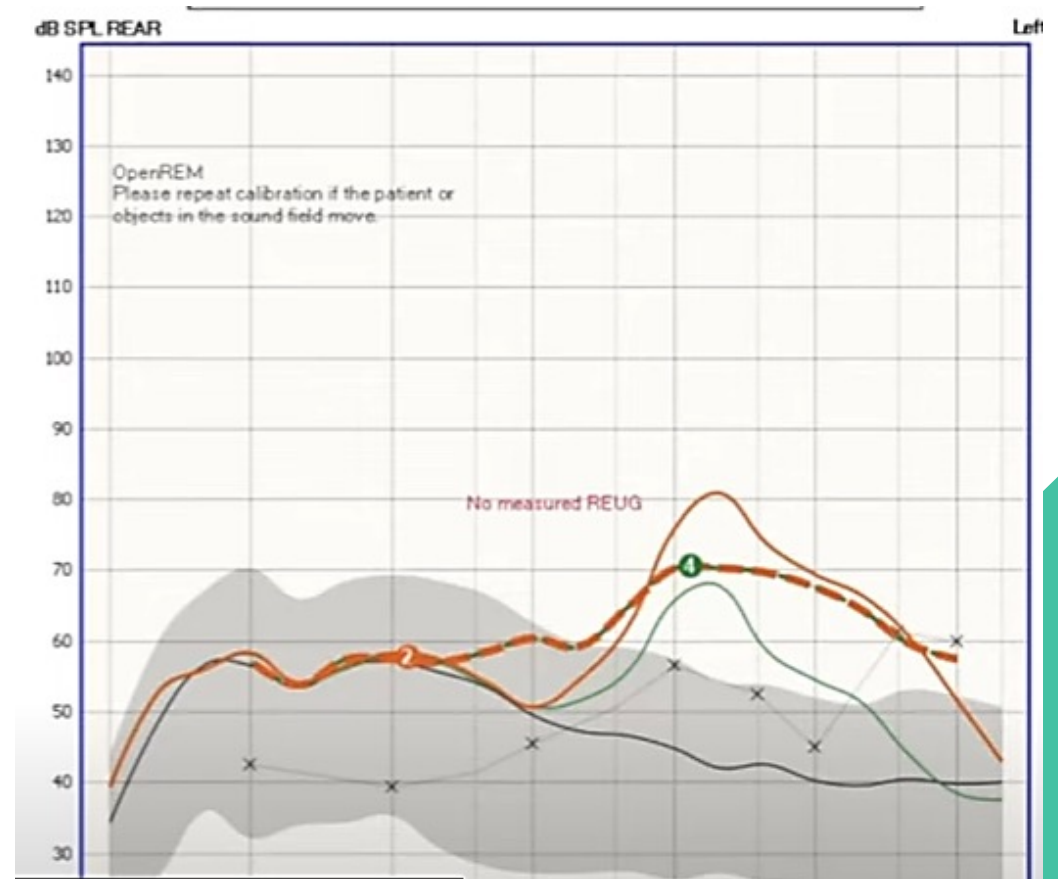
- GN Enhance Plus
- hearX Lexie B1
- Braun 102 F
- Braun BHA 100
- Novidan NoviONE
- WSA –Vibe
- Sivantos

*FDA database search Oct. 2023

Fitting the Product

Can the OTC pre-sets get close to NAL-NL2 targets?

- Some anecdotal data suggests we can get close but large errors exist.
- Concern is that users will assume that OTC's do not work and give up rather than trying another device or another program.



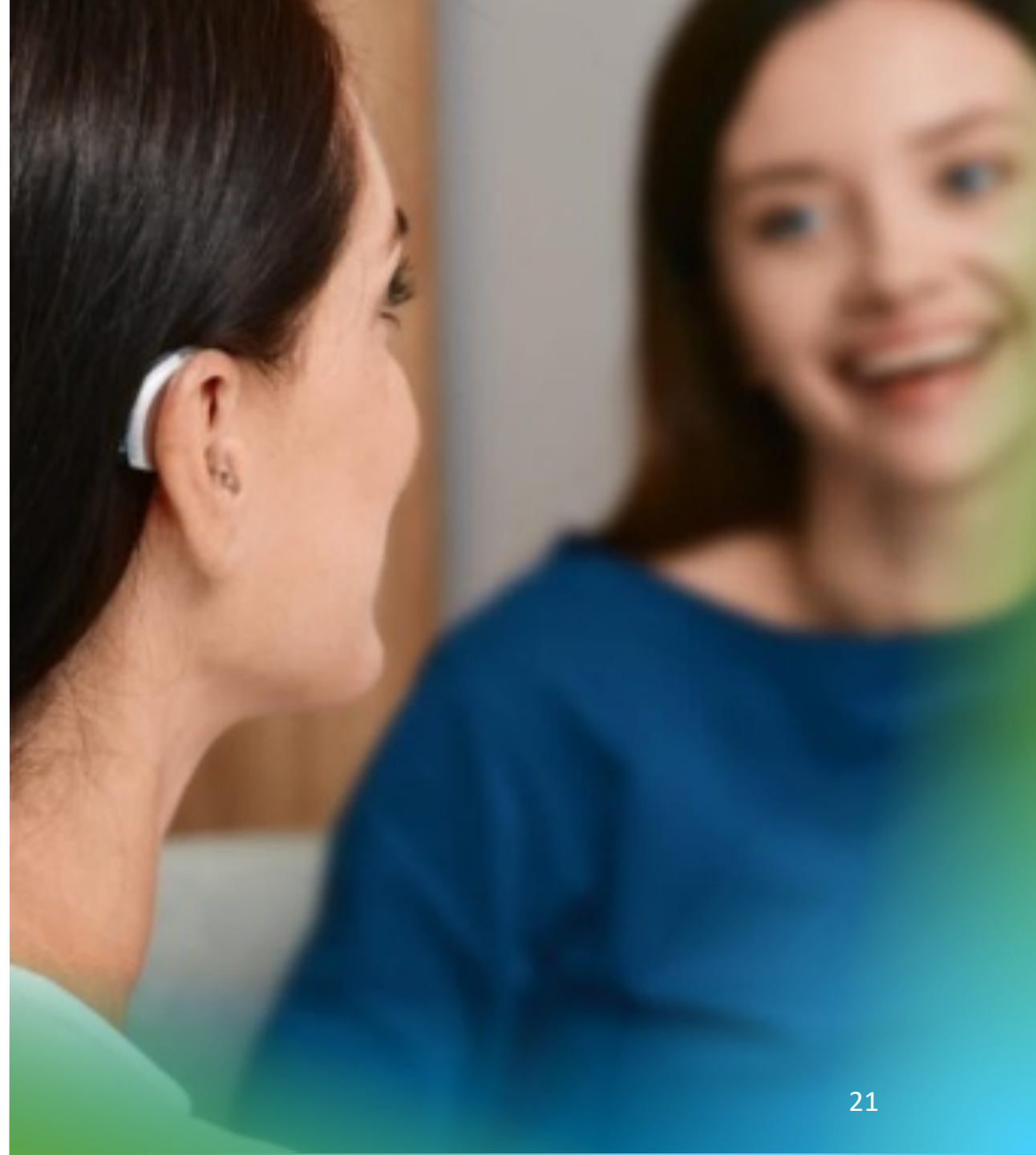
The Size of the OTC Market

Estimates of the OTC market range from 100,000 to one million units.

No organization is tracking sales, so it is difficult to get accurate numbers.

The OTC Buyer

- Is younger
- Wants a simple process (no appointment or prescription)
- Probably is a situational user (dinner, meetings, social environments)
- Inclined to purchase from a brand they recognize





Market Issues – Bad Actors

Concerns with Bad Actors

- Unsubstantiated claims
- Misleading advertising
- Failure to follow the FDA/OTC regulation





Misleading Advertising



Restore Your **Natural Hearing**

With a variety of innovative algorithms and technologies, Core One hearing aids can flexibly capture surrounding sounds and identify your environment, allowing you to engage in conversation.

Misleading Advertising

Rechargeable, Invisible, Affordable

**THE MOST INNOVATIVE HEARING AIDS OF 2023 FOR JUST
\$89 A PAIR**

Suffer from mild to severe hearing loss?
Look no further.

Introducing the TX-5 Mini.

- Company is not registered with FDA nor devices listed

Misleading Advertising

Invisible Hearing Aid Uses CIA Technology So Powerful That It Can Pick Up a Whisper Across the Room

Here's How You Can Get Them Today To Hear More Clearly And Stay Engaged in Conversations...

Most modern hearing aids have serious flaws.

- Everybody notices them - they'll make you look 20 years older the instant you put them on
- They collect sounds from behind you - which makes hearing your friends in a restaurant or crowded room impossible
- They use 10-year-old technology that amplifies everything (sometimes too loud!) - which can cause even more hearing loss!

Fortunately, there is a better way. Soundwise uses CIA technology that was specifically designed to pick up whispers so hearing your loved ones or the television so much clearer is virtually guaranteed.

No more avoiding noisy restaurants, movie theaters, or crowded places. Enjoy your friends and enjoy life thanks to Soundwise.

Plus, hearing loss is a leading cause of dementia and deadly falls among seniors. Don't become another victim!

Introducing: The Soundwise Aria
The world's most affordable, advanced in-ear hearing aid

These hearing aids are incredibly advanced and packed with new technology:

- Advanced noise cancellation
- Ultra lightweight and discrete, hides in the ear completely!
- CIA-developed digital audio enhancement
- FDA registered
- Backed by Board Certified Hearing Specialist Dr. Kenneth Nunnally
- Risk-Free Home Trial with ONE YEAR Guarantee - the only one of its kind in the industry!
- Free portable charging station so you'll never have to worry about batteries - the charge lasts 2 full days!

And the best part: it costs a fraction of what audiologists will charge you for hearing aids.

Our patients are saving 90%!!

Call 800-779-6809 or visit GetSoundwise.com/HHM

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Accessibility

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What have we learned?

Considerations for OTC - 2022

Will the success of OTC devices depend on traditional manufacturers partnering with existing consumer brands?

Will new entrants gravitate to the OTC category to avoid lengthy FDA submissions required for self-fitting devices?

Will affordability be achieved by new OTC devices, or will they compete with entry-level prescription devices?

Can self-fitting devices change the stigma around hearing aids by directly engaging the consumer?

Considerations for OTC - *2023*

Still too early
to tell

The FDA
database has
more OTC
devices listed
than self-fitting
devices
AT PRESENT

Very cheap
devices exist,
however
those that give
similar benefit
to RX devices
have
comparable
pricing

Several new
form factors –
earbuds,
eyeglasses
may change
this

Will OTC Succeed?
Time Will Tell!





Thank You!

Comments or Questions?

Contact:
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