

We recommend that FDA defines a new OTC category so that it is easily comprehensible by consumers and in line with risk class requirements for safety and effectiveness.

Category Name	Personal Sound Amplification Products	Self-Fit OTC Hearing Devices	Hearing Aids
Types of Products	Consumer Electronic	Medical Device	Medical Device
Intended Use	For non-hearing impaired consumers to amplify sounds in certain environments or leisure activities	Only for adults with mild-to-moderate hearing impairment treatable with hearing devices	For all individuals with hearing impairment treatable with hearing devices Children of 18 years or younger only through physicians & audiologists
Conditions for Sale	<i>Not regulated by FDA</i>	Available for OTC sale without the involvement of any professional	Through the support of a licensed hearing care professional
Risk Class	<i>Not regulated by FDA</i>	Not-wireless: Class I Wireless: Class II (exempt), exemption limited to one-time FDA reviewed devices	Not-wireless: Class I Wireless: Class II (exempt)