

OTC Ready™ technologies, the ideal platform for rapid market entry [update July 2024]

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The ideal platform for rapid market entry

The Food and Drug Administration (FDA) has established regulations for over-the-counter (OTC) hearing aid devices, which became effective in October 2022. According to [FDA's final rule on OTC hearing aids](#), OTC hearing aid devices are now available to consumers through retail outlets without the need to consult an audiologist for a pre-purchase hearing evaluation, selection and fitting. The objective of the new rule is to increase the public's access to hearing aids and therefore the access to improved social participation and quality of life.

FDA defines an OTC device as follows:

(A)

Are [air-conduction hearing aids](#) that do not require implantation or other surgical intervention.

[Jacoti sound personalisation is designed following audiological standards >](#)

(B)

Are intended for use by people 18 years of age and older to help with perceived mild to moderate hearing loss.

[Know more about Jacoti's focus on mild to moderate hearing losses >](#)

(C)

Allow users to control the device settings and customize the device to the user's hearing needs, through tools, tests, or software.

[Jacoti solutions have been always designed putting the user in control of their devices >](#)

(D)

May use

(i) wireless technology; or

(ii) may include tests for self-assessment of hearing loss.

[Jacoti Inside Qualcomm 51XX series >](#)

(E)

Are available to consumers over-the-counter without the supervision, involvement, or prescription of a licensed health care professional. You can buy OTC hearing aids that meet the [FDA's requirements](#) in a store or online.

[Integrating a connection between users and hearing experts through Jacoti earCloud® is possible but optional >](#)

Within the OTC hearing aid category the following device options exist:

Legacy (traditional) and wireless hearing aids which include basic features like volume control and preset programs.

This device category allows quick market entry with lower regulatory burden. Manufacturers can bring these OTC hearing aids to market without the need for a De Novo or 510(k) application with the FDA, which traditionally involve extensive study, documentation and review processes. This can accelerate the availability of new technologies and contributes to lower costs and increased accessibility for consumers seeking affordable hearing solutions.

Self-fitting hearing aids with or without a wireless feature that have greater customization through technology such as hearing tests, software, and smartphone apps.

The testing and analysis of individual hearing needs and Self-Fitting process allows for customized hearing loss compensation. This category of OTC hearing aids makes full use of Jacoti's technology suite and facilitates highest quality user experience. Jacoti has already laid the regulatory groundwork and is optimally prepared to facilitate FDA clearance for this category.

Jacoti medical regulations compliance

Jacoti is certified to the requirements of EN ISO 13485:2016 and Annex IX Chapter I and III of the EU Medical Device Regulation (EU) 2017/745 and is also registered as Medical Device Manufacturer at the USA Food and Drug Administration.

Jacoti Hearing Center is a Class II FDA listed Medical Device, classified under product code EWO. As Medical Devices, they are designed, developed and manufactured in accordance with a quality system compliant with 21 CFR Part 820 (United States quality requirements).

Jacoti maintains a close relationship and well-established communication channel with the FDA and leading U.S. regulatory consultants. We have already met with FDA regarding their final rule on OTC hearing aids and have pre-drafted applications ready for our partners.

About Jacoti

Jacoti BV | Hearing Technologies is a science-based company that develops hearing enhancement solutions embeddable in consumer devices. Its flagship product, Jacoti Inside, optimizes audio to each individual hearing requirement from consumer technologies to fully-fledged medical devices. For more information visit www.jacoti.com

Contact our Press Officer for more information or to arrange an interview with our team.
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