Jacoti HEARING WITHOUT BARRIERS

# OTC Ready™ technologies, the ideal platform for rapid market entry

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OTC Ready®

by Jacoti Staff

## The ideal platform for rapid market entry

The Food and Drug Administration (FDA) is developing proposed regulations for over-the-counter (OTC) hearing aid devices. According to the FDA Reauthorization Act of 2017, these devices will be available to the consumer through retail outlets and without having to engage an audiologist, either for a pre-purchase hearing evaluation or for the selection, fitting or verification of performance of the device.

In August 2017, Congress passed into law the OTC Hearing Aid Act of 2017.

**The OTC law passed by Congress (S934: FDA Reauthorization Act of 2017) defines an OTC device as one that:**

(A)
uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation); Jacoti sound personalisation is designed following audiological standards

(B)
is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment; Know more about Jacoti's focus on mild to moderate hearing losses

(C)
through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customise it to the user's hearing needs; Jacoti solutions have been always designed putting the user in control of their devices

(D)
may–
(i) use wireless technology; or
(ii) include tests for self-assessment of hearing loss; Jacoti Inside Qualcomm 51XX series

(E)
and is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. To be connected with a hearing expert through Jacoti earCloud® is optional after the device purchase

## Jacoti already complies with the necessary medical regulations

Jacoti is certified to the requirements of EN ISO 13485:2016 and Annex II (excluding section 4) of the EU Medical Device Directive and is also registered as Medical Device Manufacturer at the USA Food and Drug Administration.

Jacoti ListenApp is a Class I FDA Registered Medical Device, classified under product code ESD, and 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 regulatory

Suggested readings:
Consensus paper from hearing care associations (2018)

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### 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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