

First user-fitted hearing aid approved

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(HealthDay)—The first hearing aid that doesn't require the assistance of an audiologist or other health care provider has been approved by the U.S. Food and Drug Administration.

The Bose Hearing Aid is a user-fitted [device](#) for people aged 18 and older with mild-to-moderate [hearing](#) loss, the agency said Friday in a

news release.

"Today's marketing authorization provides certain patients with access to a new hearing aid that provides them with direct control over the fit and functionality of the device," said Dr. Malvina Eydelman, director of the FDA's Division of Ophthalmic, and Ear, Nose and Throat Devices.

Some 37.5 million adults in the United States report having hearing loss of some degree, the FDA said. Common risk factors include aging, exposure to loud noises and certain medical conditions.

The Bose device was evaluated in clinical studies involving 125 people. When participants self-fitted the device and used a cellphone app to program and make adjustments to the device settings, they "generally preferred those [hearing aid](#) settings over ... professionally-selected settings," the FDA said.

While users may fit, program and control the device on their own, some state laws require that hearing aids be obtained from a licensed dispenser, the agency said.

Bose Corp. is based in Framingham, Mass.

More information: The FDA has more about [this approval](#).

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