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FDA Breakthrough Device Designation for Sofi® Hearing Assessment System

We're very pleased to share that the FDA has granted the Breakthrough Device Designation to the Sofi® Hearing Assessment System – a major milestone for MindAffect and a great way to kick off 2026. This designation is awarded to only a fraction (~5%) of medical devices each year and according to publicly available information it has never been awarded to a hearing diagnostic system since the program started in 2015. This designation is based upon the FDA's assessment that Sofi meets three key criteria:

1. Addresses a massive unmet clinical need:

Millions of people, especially toddlers, individuals with developmental or cognitive impairments, and older adults with neurological conditions or movement disorders, struggle with traditional behavioral hearing tests. As a result, hearing loss in these populations is often under-diagnosed or diagnosed too late, leading to permanent developmental disabilities, cognitive decline, and a significantly increased risk of early-onset dementia. With an estimated global cost of \$1Trillion per

year, major global organizations including the FDA, WHO and NIH have declared unaddressed hearing impairment a global priority.

2. Has potential to substantially improve the existing standard of care:

Today's hearing assessment relies either on patient cooperation or on lengthy, specialist-led clinical testing requiring anesthesia. Sofi provides objective, automated results in minutes while the patient relaxes watching a video. Its ease-of-use and portability allow accurate hearing assessment to reach far beyond specialist clinics, from community settings to the home, dramatically expanding access to care (while lowering costs).

3. Supported by compelling scientific and early clinical evidence:

The FDA's decision reflects confidence in Sofi's scientific foundation and the pre-clinical data results thus far which demonstrates Sofi's potential to accurately deliver meaningful improvements in patient assessment.

What this enables: Breakthrough status allows us to engage with the FDA earlier and more frequently to receive faster and more targeted feedback, and to align more efficiently for the remaining evidence we need. This should help us accelerate our path toward FDA clearance by ~6-8 months. While regulatory standards remain just as high, the process should become more collaborative and predictable, and we are targeting our 510(k) milestone by Q2 2027.



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