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Envoy Medical Receives FDA IDE Approval to Begin Early Feasibility Study of Acclaim® Cochlear Implant

The First-of-Its-Kind Fully Implanted Acclaim Cochlear Implant Received Breakthrough Device Designation

WHITE BEAR LAKE, Minnesota – June 21, 2022 – [Envoy Medical® Corporation](#), a hearing health company focused on providing innovative technologies across the hearing loss spectrum, today announced the U.S. Food and Drug Administration (FDA) approved its Investigational Device Exemption (IDE) application to begin a clinical trial with its fully implanted Acclaim® cochlear implant. Envoy Medical's single-center Early Feasibility Study for the Acclaim will take place at Mayo Clinic in Rochester, Minn. The Acclaim is unlike current commercially available cochlear implants due to the lack of any externally worn components and it was granted Breakthrough Device Designation in 2019 by the FDA. If approved by the FDA, the Acclaim would be the first-of-its-kind cochlear implant designed to be fully implanted and use the ear, rather than a microphone, to pick up sound.

Colin Driscoll, MD, practicing neurotologist, professor of otolaryngology – head and neck surgery at Mayo Clinic, is principal investigator for this study and Aniket Saoji, Ph.D., associate professor of otolaryngology – head and neck surgery at Mayo Clinic is co-investigator. Both investigators serve on Envoy Medical's Cochlear Implant Advisory Board.

Of the estimated 1.4 to four million potential people with significant hearing loss in the United States who could benefit from cochlear implants, roughly five percent of eligible candidates use cochlear implants.¹ Potential adult recipients often wait longer than they should to get existing partially implanted cochlear implants, and a reason often cited is the amount of external hardware.²

“We believe that a fully implanted cochlear implant may increase their use among millions of adults with significant hearing loss,” said Brent Lucas, CEO of Envoy Medical. “This study is the first step in evaluating the safety and effectiveness of the fully implanted Acclaim cochlear implant, putting us closer towards potentially filling a large unmet need in hearing loss technology.”

Designed to address the limitations of current microphone-based hearing devices, Envoy Medical's fully implanted technology includes a completely unique sensor designed to leverage the natural anatomy of the ear instead of a microphone to capture sound.

Patients interested in learning more about the study should contact Amy Pajula, customer experience manager, at apajula@envoymedical.com for more information.

About the Fully Implanted Acclaim® Cochlear Implant

The fully implanted Acclaim® cochlear implant is a first-of-its-kind cochlear implant designed to address the hearing of adults diagnosed with severe to profound sensorineural hearing loss. The Acclaim cochlear

¹ Cochlear Implant Candidacy for Adults. <https://www.acialliance.org/page/AdultCandidacy>

² Barnett, M. et al. Factors involved in access and utilization of adult hearing healthcare: A systematic review. *Laryngoscope* (2017). doi:10.1002/lary.26234

implant is designed to leverage unique sensor technology from the fully implanted Esteem active middle ear implant. The Esteem was FDA-approved in 2010.

If approved by the FDA, the Acclaim would be the first-of-its-kind cochlear implant designed without any externally worn components and to use the ear to pick up sound.

CAUTION The fully implanted Acclaim cochlear implant is an investigational device. Limited by United States law to investigational use.

Important safety information for the Esteem can be found at: <https://www.envoymedical.com/safety-information>.

About Envoy Medical Corporation

Envoy Medical Corporation, headquartered in White Bear Lake, Minnesota, is a privately held hearing health company focused on providing innovative technologies across the hearing loss spectrum. Envoy Medical has pioneered one-of-a-kind, fully implanted devices for hearing loss, including its fully implanted Esteem® active middle ear implant, commercially available in the U.S. since 2010, and the fully implanted Acclaim® cochlear implant, an investigational device. Envoy Medical is dedicated to pushing hearing technology beyond the status quo to improve access, usability, compliance and ultimately quality of life. For more information, please visit: www.envoymedical.com and @envoymedical on [Facebook](#), [LinkedIn](#) and [Twitter](#).

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