
Sophono Hearing Devices Cleared for MRI



Sophono, Inc., the manufacturer of abutment-free, implantable, bone conduction hearing devices – has received clearance from the U.S. Food and Drug Administration for magnetic resonance imaging (MRI).

With the clearance, patients in the United States who have the Sophono Alpha 2™ System can undergo MRI – in both 1.5 and 3-tesla magnetic fields – without removing the magnetic implant. In January, the Sophono Alpha earned clearance for use in an MRI field for device wearers in Europe and other countries around the world by passing tests from ASTM International, the globally recognized leader in the development and delivery of international voluntary consensus standards.

"Worldwide clearance of the Alpha 2 device for MRI gives patients and providers full assurance that the Sophono Alpha implant will not need to be removed should the patient need to undergo MRI testing at any point in the future," says Jim Kasic, president and CEO of Sophono. "The absence of contraindications for MRI with the Sophono Alpha System is a great step forward for patients, as well as the physicians, audiologists and clinicians who serve those with hearing loss."

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