FDA Approves High Intensity Focused Ultrasound for Bone Tumors

This technique can relieve pain related to osteoid osteoma.

November 27, 2020 By Food and Drug Administration (FDA)

On November 27, 2020, the Food and Drug Administration approved the Sonalleve MR-HIFU system (Profound Medical Inc.) for the treatment of osteoid osteoma in the extremities.

MR-guided High Intensity Focused Ultrasound (MR-HIFU) treatment is an image guided technique combining high intensity focused ultrasound ablation with real time monitoring of temperature change during the sonication.

The clinical results support the probable benefit of Sonalleve MR-HIFU system for the ablation of painful osteoid osteoma. Efficacy was evaluated in a study of nine patients treated with MR-HIFU, without technical difficulties or serious adverse events. There was a statistically significant decrease in their pain scores within 4 weeks of treatment. No pain medication usage was achieved in 8 of 9 patients after 4 weeks.

The device should not be used under certain conditions. For full information including warnings and precautions, view the Summary of Safety and Probable Benefit Document for the Sonalleve MR-HIFU system.

Summary of Safety and Probable Benefit Document for the Sonalleve MR-HIFU system.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

For assistance with single-patient INDs for investigational oncology products, healthcare professionals may contact OCE's Project Facilitate at 240-402-0004 or email OncProjectFacilitate@fda.hhs.gov.

This announcement was originally published on the Food and Drug Administration website on November 27, 2020.

© 2026 Smart + Strong All Rights Reserved.