FzioMed files citizen petition for reconsideration following FDA rejection of its spinal gel PMA

Mass Device

Privately held medical device maker FzioMed urges the FDA commissioner to reconsider its premarket approval bid for the Oxiplex spinal gel after the application was rejected by the federal watchdog agency.

California device maker FzioMed filed a citizen's petition with the commissioner of the FDA, asking the agency to re-open a rejected premarket approval application for its Oxiplex spinal surgery gel.

FzioMed had originally filed its PMA for Oxiplex in October 2007, getting a "not approvable letter" back in July 2008 after the FDA determined that FzioMed hadn't provided sufficient evidence of the gel's effectiveness in aiding in healing following lower back spinal surgery.