

FDA's New Guidance on Wireless Medical Devices



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By

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This column's author has some hands-on experience in this subject, having been involved in obtaining marketing clearances by 510(k)s for one of the first wireless devices; two versions of a cardiovascular balloon catheter inflation device, where the pressure readout was sent to a screen by means or through a wireless signal; one submission in the early 1990s; and a second one in the early 2000s for a different client. Since then, the technology has evolved and improved and has found its way into many different devices with many different avenues of use. FDA, recognizing the growing use of wireless...

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