Implanted Blood Access Devices for Hemodialysis—FDA's Draft Guidance

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A review of this document is also useful for other type devices' specification developers and/or manufacturers. It provides additional insight into the areas that are among the highest concerns within the FDA's Center for Devices and Radiological Health (CDRH) and which should be addressed in other device 510(k)s, as applicable. The majority of information contained in this column is taken directly from this draft guidance document. The actual document can be found here and here. Introduction FDA has proposed to reclassify implanted blood access devices for hemodialysis, which are currently...