Medical Device Forum: Product Changes and the 510(k)

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Changes requiring a new 510(k) are a source of much confusion If a device has significantly changed, a new 510(k) is required The cumulative effect of multiple minor changes may cause the manufacturer to decide that a device has been significantly changed The US Food and Drug Administration does not intend for every change to require a new submission, but that every change be evaluated for such a possibility Manufacturers may incorrectly use “Indications for Use” and “Intended Use” terminology Examples of modifications that may require a 510(k) submission are listed Manufacturers must...