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The premarket notification a.k.a. 510k: Using substantial equivalence to your advantage!

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The premarket notification, better known as the 510 K, is the most common regulatory pathway medical device manufacturers use to bring new medical devices to market. But because of a few highly publicized problems with some medical devices, 510k submissions are experiencing greater regulatory scrutiny prior to clearance. Although most submissions are eventually cleared, nearly 75% of first-time 510 k applications are rejected leading to review times of 114 days in 2014. This creates costly delays for medical device manufactures – many of which could be minimized if not avoided completely! One of the areas receiving the greatest regulatory scrutiny is the substantial equivalence argument. Simply put without a strong substantial equivalence argument, your 510k submission may not be successful. But what does substantial equivalence really mean and how do I show it? How do I use not just what the regulation says but also what it does not say to my advantage? Using the case study approach, these questions and others will be presented in an interactive fashion. Following this presentation, participants will:

- understand the regulatory requirements of substantial equivalence and how to use them to your advantage
- learn to design a substantial equivalence regulatory strategy using regulatory logic and how to defend it
- appreciate the split- and multi-predicate strategies and how and when to use each
- be aware of several new FDA guidance documents and how to use them to your advantage
- discuss the proposed changes currently under debate and what the future may hold for the 510 K program

Bottom line: Knowing what the regulation says, although it's a good start, is not enough – you must know how to use it to your advantage!

Biography

Michael Drues, PhD, is the President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including (but not limited to): stimulating & innovative educational programming, brain-storming sessions, prototype design, product development, bench top & animal testing, regulatory strategy & clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment. He received his BS, MS, and PhD degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the US Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world. He is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the US Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world. Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, he teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination

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