

## Client Alert January 2012

### 510(k)s/IDEs: The New Normal?

#### DEAR CLIENTS AND FRIENDS OF THE FIRM,

In this CLIENT ALERT we offer you a four part series (contained in one document) covering our thoughts on the current 510(k) and pre-IDE programs. We provide some practical insights on what it is like to approach FDA today on a 510(k), whether you start with a pre-IDE meeting or you get into a clinical discussion after a 510(k) submission. This CLIENT ALERT is longer than most, but is full of practical insights and inside advice. Here is the Table of Contents:

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## **Part I**

### **FDA's Stage-Gating Review of 510(k)s**

As many of you have encountered by now, FDA is not exactly shy when it comes to requesting clinical data for 510(k)s. Requests for clinical data are becoming the norm, rather than the exception. Today CDRH has a stage-gating approach to the review of 510(k)s. They first review the file to determine if it meets the criteria for a 510(k), i.e. is there is a predicate, does the subject device have the same intended use and technological characteristics. If there are different technological characteristics, do they raise “new types” of questions of safety and effectiveness? If FDA review staff believes you do not meet these 510(k) criteria, they send a letter stating that they have not reviewed the file substantively because FDA believes you do not (may not) qualify for the 510(k) pathway.

The goal of review staff is to avoid wasting staff time in a substantive review of the data if staff believes, analytically, there is no predicate. This analysis and letter usually takes 30-45 days off the 90-day “510(k) clock.” It sets up the company for an appeal of these legal/regulatory/scientific issues. The problem is that this has become the new norm for many 510(k)s that add some technological feature(s), i.e. a legal/regulatory squabble, which often involves an appeal to management. You must win this issue to remain on the 510(k) path—an important step—and proceed to a dialogue about the content of your submission. If you remain on the 510(k) path then your data can be substantively reviewed.

Upon a substantive review of the data, if there are deficiencies in the data (and FDA always finds some) or questions, your company will receive an Additional Information letter(s). This is when the real dialogue/debate about safety and effectiveness begins. FDA reviews the quality and quantity of the performance data the company has submitted in support of their submission. It is here that FDA either finds deficiencies in the clinical data submitted or, if there are no clinical data, starts to suggest that clinical data may be needed. Sometimes the discussion about the need for clinical data is straight forward and declarative. Other times it is passive aggressive with reviewers hemming and hawing around before finally getting to the point, needlessly wasting valuable review time and company resources. The next legal/regulatory issue a company encounters at this level is that CDRH is often looking for data to establish safety and effectiveness in an absolute sense as with a PMA, instead of in a comparative sense (to the predicate), which is the standard for a 510(k). Industry often must push back at this level to keep FDA reviewers on track. This is where Least Burdensome arguments also become important.

Our firm handles many of these appeals and wins a high percentage of them. The good part of a win is that management applies common sense in overturning the review staff. The bad part is that it takes an appeal to get common sense applied. Reviewers clearly need more training in the law to understand the 510(k) standard, Least Burdensome principles and that the FDA's statutory role is twofold: to protect patients *and* speed innovations to the marketplace. Most reviews at the staff level are heavily weighted

toward risk analysis and the benefits of devices are often slighted because of their risk-averse approach to conducting reviews. Young inexperienced reviewers see boogeymen in every submission. That is why most devices are cleared or approved and on the market 3 to 4 years in Europe before they are in the U.S. market.

## **PART II**

### **What is Producing These Clinical Requests?**

To discuss clinical data requests we have to wrap our mind around what is producing these requests for clinical data. To do so requires a brief examination of the 510(k) standard of “substantial equivalence.” It also requires a brief discussion of the types of technology FDA is confronting today, why clinical data questions arise, the Least Burdensome principles and some strategies for pre-IDE meetings/discussions. This Client Alert also discusses some ideas of what companies can expect when clinical data requests are made. Let’s address these topics one at a time.

#### **--The 510(k) Standard in a Nutshell**

As you know, the 510(k) pathway is reserved for moderate risk, Class II devices. Most medical devices today are cleared under the 510(k) provisions. With a 510(k) all the sponsor needs to show is that the device is “substantially equivalent” (SE) to a predicate device that has been on the market, known as a “pre-amendments device.” The rationale is that there are devices that have been safely on the market and a sponsor need not reprove the safety of the new device in an absolute sense, like with a PMA. Instead, the sponsor must show the device is as safe and effective as the “predicate” to which it has claimed substantial equivalence. A PMA device cannot serve as a predicate, only another 510(k) device can.

The focus of the 510(k) is on the comparison between the predicate and the new device. The questions to be answered are as follows: 1) does it have the same intended use, and 2) does it have the same technological characteristics, and 3) if it does not have the same technological characteristics, do the new features raise any unanswered questions of safety and effectiveness? FDA essentially borrows/draws from the knowledge it has of the predicate device(s) so that data are not needlessly regenerated when the medical device to which it is being compared involves well-established technology. The 510(k) system embodies the idea of administrative efficiency—for both FDA and industry. Smart science means not reproving what is already known.

To state that obtaining a 510(k) is dramatically simpler than obtaining a PMA is bit of a misnomer today because 510(k)s today require a lot of substantiation and often look like a PMA and get a significant amount of FDA review scrutiny before coming to market. Today’s 510(k)s are often called “PMA-lite.” Historically, the FDA did not typically require a company to submit clinical trials for a 510(k) to establish the safety and effectiveness of the device and obtain FDA review and approval before coming to the market, like with a PMA. Today, FDA often requires clinical data (sometimes

prospective, randomized trials) for a 510(k) but the trials will not be as large and expensive as for a PMA.

**--FDA is Seeing Many New Technological Differences.** In fairness to FDA, 510(k) sponsors are submitting 510(k)s in endless combinations of technological innovations. That is the beauty of the 510(k) program; it is sufficiently flexible to accommodate technological innovation as long as it involves incremental evolution and not large technological leaps. Companies today are submitting combinations such as 1) existing *materials* in different anatomical and/or therapeutic uses; 2) existing *engineering concepts* in different anatomical and/or therapeutic uses; 3) combinations of materials and engineering concepts (in new anatomical and/or therapeutic uses); 4) the addition of antibiotics, antimicrobials, OTC drugs, etc.; and 5) many others. All of these new and interesting combinations are not necessarily novel in the PMA sense, but do challenge the FDA and the 510(k) framework in that they are not conventional, generic-like copies of existing devices. But, as stated above, the 510(k) program is designed to accommodate technological advances and hence the term “substantially” equivalent. The labeling and the technological features need not be identical. Still, these changes can raise interesting questions upon FDA review. That is why FDA’s default position is to request more data and it often asks for clinical data along with the typical non-clinical performance data.

**--Why Clinical Data Requests Arise—New “Types” of Questions.** The reason data are needed, under the 510(k) framework, is if the technological characteristics of the subject device *differ* from the predicate then the next question is whether the differences raise “*new types*” of questions of safety and effectiveness? FDA reviewers often take a limited view of what is a “new type” of question for purposes of FDA’s review. Is the question new for the specific device under review (the technology family, if you will) or is it new to the FDA overall? For example, does the use of a material in a new orthopedic use raise new types of questions if it has been used elsewhere in the body and is known to be biocompatible? What types of new questions does it raise or does it really raise old questions in a new context? Are there existing performance tests which can answer these questions? To illustrate, does the use of a self-expanding material like nitinol used in one part of the anatomy (e.g., the vasculature) raise new types of questions when used in a new part of the anatomy (e.g. in bone) if the FDA has seen similar questions and there are performance tests in existence which can answer them?

The FDA should not be limited to viewing “new” with respect to the subject device and the predicate family in front of them. FDA should be allowed to consider “new” in the context of its overall repository of institutional knowledge. For years we have argued to CDRH that it is consistent with the 510(k) statute and in the interest of administrative efficiency for FDA to look at other *non*-predicate devices to determine if it raises a new type of question. In other words, FDA should be able to consider the technological and performance aspects of a device that has similar technological characteristics seen by the FDA before, even though not in the predicates themselves. It now appears that the FDA seems to agree.

**--FDA's Newly Proposed Guidance Document Covers "Reference Devices."** FDA has recently proposed a guidance document that allows a sponsor to draw upon devices that are "technological precedents," as opposed to "predicates." The distinction between a precedent and a predicate is a critical one. These technological precedents are referred to in the newly proposed by FDA guidance as "reference devices." This is how FDA describes a reference device in its newly proposed guidance:

In certain circumstances, where appropriate, a manufacturer may refer to legally marketed devices that have a different intended use or different technological characteristics that raise different questions of safety and effectiveness, to address specific scientific questions for a new device. *If a manufacturer successfully navigates through Decision Point 4 on the Flowchart using a primary predicate device, other legally marketed devices, which FDA calls "reference devices," may be used to address certain performance characteristics of the new device.* If a manufacturer intends to use a reference device, the manufacturer should provide a scientific rationale that justifies its use. *A reference device is not considered to be a predicate device.* This concept is illustrated in the Reference Device Scenario below. We recommend that you read this Scenario side-by-side with the Flowchart in Appendix A so that you can follow the decision-making process.

*See, Draft Guidance for Industry and Food and Drug Administration Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications, December 27, 2011(emphasis added) (hereinafter the "New 510(k) Guidance").*

FDA's adoption of this concept is extremely important and encouraging. FDA has this vast repository of institutional knowledge upon which it can draw to make determinations of SE. The ability to use "reference" devices, in addition to predicate devices, helps manufacturers make the argument that their technology may be new, but it creates questions asked by FDA and answered by industry before. In a 510(k) review, FDA will now look at the performance characteristics of the predicate device(s) and reference devices to ascertain the safety and effectiveness of the subject device. The New 510(k) Guidance document has embraced this analytical concept which gives FDA reviewers the authority and confidence to know they can draw upon information outside of the predicate family of devices in making SE determinations. The scope of what is unknown about any subject device shrinks when FDA is allowed to consider reference devices as well.

**--The Bottom Line is that Technological Issues Raise the Specter of Clinical Trials.**

Even if you win your legal/regulatory/scientific issue on appeal that there are no new types of questions of safety and effectiveness, review staff re-inherit the file from management to conduct a substantive review of the performance data. If FDA has not seen your combination of claims, materials and/or engineering concepts, FDA may want more than performance data (bench, animal, biocompatibility, etc.) to be convinced that your device is as safe and effective as the predicate.

## PART III

### Negotiating on Clinical Trials Using the Least Burdensome (LB) Principles

When we negotiate with FDA regarding clinical trials, we work with clients to propose more practical data solutions than that being considered by review staff. Frequently, review staff will look at a clinical study design offered by a manufacturer that simply needs to be small and confirmatory of very solid performance data which already demonstrates the device is SE. The staff will often respond in a predictable, almost boilerplate-like fashion by countering with a randomized, controlled clinical study (RCTs) with a large “n” and saying that “if you did this study, it would make our job easier,” as if that is why industry submits data. Of course submitting an RCT would always make a reviewer’s job easier, but industry’s goal is not to make a reviewer’s job easier. Nor is it required under the statutory LB principles. Rather, it is to provide the amount of data necessary to establish SE to the predicate(s) device, i.e. to prove it is as safe and effective as the predicate(s), and no more.

**--Congressional and Industry Pressure is Mounting.** FDA seems to be responding to Congressional pressure to adopt Least Burdensome (LB) principles—at least at the level of the Center Director’s Office. Congress has introduced legislation to flesh out and expand upon LB principles to counter the FDA trend of ever-escalating data requirements due to its risk-averse approach to approving/clearing devices. There is strong bipartisan Congressional support that devices are getting approved first in Europe and years later (3 to 4 years) in the United States. This is because the FDA is so risk-averse that it is requesting more data than are truly needed to clear and approve devices. The Center Director and those within his office continue to discuss the importance of LB in public speeches to the public, industry and to Congress, but there is little evidence that the application of LB principles are making their way past Division Directors (and often there is no evidence they have even reached that level).

**--Management Podium Talk Does Not Translate into Reviewer Walk.** LB principles certainly are not making their way into the thinking of review staff who continues to ask for data they **want**, not what they **need**, to make a SE determination. This again stems from the fact that reviewers are 1) by nature, risk averse; 2) skeptical about industry; 3) more worried about making a mistake, than doing what is right; 4) they do not have the mentality of collaborating with industry to help beneficial innovations to come to the market, many act as gatekeepers; 5) reviewers are not rewarded for taking reasonable risks. FDA and CDRH management pay extraordinary attention to “managing up” to Congress, the Administration and the press. CDRH management talks a good game about LB principles, but does little to “manage down” into its organization by training, empowering and encouraging Division Directors, Branch Chiefs and reviewers to help devices to obtain clearance or approval based upon LB principles. This is not to say all reviewers, Branch Chiefs and Division Directors are alike. There are some bright rays of hope among them.

--**Alternatives to RCTs—the Least Burdensome Guidance Documents.** CDRH has some terrific LB guidance documents developed between 1999 and 2002 that have fallen into complete disuse by the Agency. We use the words in these documents to remind the Agency of positions they have previously taken. For example, in several guidance documents FDA reminds itself and industry that clinical trials should not be required for most 510(k)s, but when a clinical trial is necessary, there are alternatives that should be considered to RCTs:

*Clinical data are not required for most 510(k)s.* Consequently, the Agency should clearly document the issue that warrants a request for such data. In deciding how clinical data should be obtained, FDA and Industry should consider alternatives to randomized, controlled clinical trials, as discussed above for PMAs, when potential bias associated for alternative controls can be addressed. *Alternatives such as reliance on valid non-U.S. data, use of meta analyses, and trial designs employing non-concurrent controls such as historical controls (e.g. literature, patient records), OPC and patients as their own control should be considered to determine if they may be appropriately used.*

*See, The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry, at 5, October 2002 (emphasis added).*

An earlier LB guidance document asks CDRH reviewers to closely interrogate into the need for clinical trials. If clinical data are needed, then the reviewer should ask themselves what study design and size will suffice without adding unnecessarily to expense or delay. *See, Guidance for Industry and FDA Reviewers on “Evidence Models for the Least Burdensome Means to Market,” September 1999.* These are concepts/considerations which seem completely lost upon reviewers today. FDA reviewers seemed detached or oblivious to the effect that their, sometimes cavalier, boilerplate requests for more data have upon an industry that is not an endless fount of investment capital. Worse yet, some reviewers feel philosophically compelled to require an “evil” industry to submit as much data as they deem necessary to protect the American public.

Asking for more data must be in the context of relative risk and the benefits the device will provide society, i.e. the loss to society if the barrier to entry is too high. For example, if FDA continues to treat relatively innocuous combinations of OTC drugs impregnated into wound dressings as combination products subject to full-blown drug approval standards, the U.S. may not enjoy the benefits of these devices that can reduce infections, promote wound healing and the like. This is because the level of investment, does not match the financial margins a company must make to develop and commercialize this type of device since it will be too expensive.

The 1999 LB guidance document mentioned above requires the following analysis:

In general, these considerations are addressed by following an approach that determines:

- 1) ***What information is already known*** about this medical device for this specific intended use?
- 2) ***What additional information can be applied*** to this device from the data available ***for both this and other devices?***
- 3) ***What further data***, in addition to the information identified above ***are necessary*** to provide reasonable assurance of safety and effectiveness for this device (for a PMA device) or to establish substantial equivalence (for a 510(k) device)?
- 4) ***If new clinical data are found necessary, then how many patients and what type of study design will have a reasonable likelihood of resulting in data that may support the approval or clearance of the device without unnecessary delay or expense?***

*See, Guidance for Industry and FDA Reviewers on “Evidence Models for the Least Burdensome Means to Market,” at 4, September 1, 1999 (emphasis added).*

These are some of the documents and quoted sections manufacturers can use in their review team discussions and appeals to FDA management when discussing clinical trial requirements. ***There is some evidence that in the last three to four months that FDA is becoming more receptive to LB arguments and creative alternatives to full blown RCTs and that too is encouraging.***

## PART IV

### The Role of Pre-IDE Meetings Today

When a company strategizes about whether to conduct a clinical trial for a 510(k), it often considers the role of a pre-IDE meeting. The use of pre-IDE meetings for 510(k)s came into vogue in the last four to five years and companies have typically used the meeting in one of two ways. First, the goal would be to obtain feedback on whether a 510(k) submission really was the appropriate path and to inquire whether clinical data would be needed and, if so, a ballpark idea of how much. Second, companies that knew clinical data would be needed for clearance or wanted clinical data for marketing/reimbursement reasons, would have a pre-IDE meeting to obtain feedback on (and hopefully confirmation of) their proposed trial.

**--Pre-IDE Meetings Are Not Working Well.** The problem is that pre-IDE meetings have failed of their essential purpose. CDRH has turned these meetings from a helpful, expeditious dialogue/feedback into a meeting that takes forever to schedule, provides equivocal, non-committal feedback or feedback that requires a trial far in excess of that needed (sometimes called “overkill”), and often results in a non-approval or a seriously

delayed approval of the IDE. The focus of IDE meetings should be on the safety of the patient. FDA gives itself far too much discretion to hold-up trials which often have IRB approval (often from multiple institutions). This is why clinical trials are now being taken offshore to Europe, India or Latin America where commencing a clinical trial is much easier. The dialogue justifiably gets into the realm of effectiveness as it relates to whether the study, as proposed, is likely to lead to clearance if the endpoints are met. But FDA's view on the quantum of data required to obtain clearance is an ever-escalating target. FDA continues to introduce heavy biostatistical principles into the discussion which predisposes the dialogue to large studies, often with an RCT design, when a robust observational study might suffice.

The pre-IDE process has become a clearance/approval process unto itself before the company ever gets to run FDA's gauntlet with an actual 510(k) submission. Pre-IDE decisions that used to run between two to three months now can easily be stretched out from 7 to 12 months, and sometimes 18 months or more. *The irony is that companies often decide to avoid the battle with FDA over whether clinical data are needed and, by way of compromise, offer a proposed trial upfront only to encounter an FDA that cannot give timely, definitive feedback and usually wants far more data.* FDA's desire for more data is insatiable and is usually far more than is needed under LB principles. Companies languish forever in pre-IDE proceedings unable to commence their trial because FDA won't approve the IDE or FDA gives such equivocal, non-committal feedback, that conducting the trial runs the risk that it will fall short of FDA's expectations. For start-up companies, these delays consume unexpected and unnecessary amounts of investment capital and make it hard to obtain additional, subsequent funding due to the uncertainty of the IDE/510(k) process today. For well-established companies, it is equally frustrating, but not as cash-critical.

**--What If You Come Into a Clinical Discussion With FDA After Your 510(k) Submission?** Sometimes companies deliberately choose not to have a pre-IDE meeting with FDA because they were forewarned how long and arduous the process could be. We often tell our clients why waste the time on a pre-IDE meeting when you could lose a valuable 9-12 months arguing over whether you have the *right* to commence a clinical trial. This can delay a 510(k) submission for an unacceptably long period of time. We often recommend either foregoing a clinical trial and see if you can obtain clearance with your performance data alone and/or use retrospective clinical data. Or the company could do a prospective study in Europe or elsewhere (assuming thought goes into a fairly robust trial design) to avoid filing an IDE with FDA. With the time saved that you would lose trying to proactively obtain an IDE, you can discuss with review staff (and not IDE staff) what their clinical requirements might be. The company can do this in the context of a 510(k) submission and outside of the formal IDE review process. The company can then submit this additional data as part of its 510(k) in the hope of securing clearance.

*The reason not to have an IDE meeting or submit clinical data upfront is twofold. First, if you request an IDE meeting with FDA it is like inviting them to your development team.* The company asks FDA for input on the trial design they would recommend (hopefully your design, not a blank slate). While that is superficially

appealing, in most cases it will end up being a frustrating and never-ending exercise. As much as industry and FDA romantically believe that they can “partner,” it never works well in reality. Even if you have a trial design in mind they will make a Cadillac out of any reasonable request. Your well-thought out proposal which you believe is essentially a “go” simply becomes FDA’s starting point.

We don’t know exactly why that is except it seems to be a matter of psychological superiority. It is in FDA’s nature to want to be the expert on all things clinical/ biomechanical and have the final word. We cannot remember one time in all of our IDE/510(k) meetings on behalf of clients where FDA has accepted our client’s initial proposal, no matter how well designed, without attempting to suggest fairly significant changes. This is unfathomable. Hasn’t FDA ever seen a trial design they liked and for which they did not recommend changes? It is really the case that the entire medical device industry is incapable of designing a trial that is sufficient to demonstrate substantial equivalence? No matter how young and inexperienced the reviewer, they *always* know better than some of the most experienced clinical/regulatory/medical experts in industry and clinical practice/academia. Maybe it is a socialistic bent that government always knows better and will act to protect patients from the greedy, profit-taking industry folks whose opinions (designs) cannot be trusted.

*The second reason not to submit an IDE or clinical data upfront is that if the clinical discussion comes in after the 510(k) submission you can then have the discussion with review staff and try to avoid the formal IDE process.* This can work well when you have a good reviewer who is open-minded and flexible. You can ask them not to put you into the formal IDE process which, as we established earlier, can derail the process. Rather, it is better to continue the clinical discussions with your assigned 510(k) review staff. They know the device and the data. If you pursue the pre-IDE route, the company would virtually have to start over with a new group of people assigned to the pre-IDE staff for your device.

*The third reason not to submit an IDE or have a pre-IDE meeting is the process has become interminably long, overly-complicated and results in advice that is equivocal and not definitive, at best.*

**--Holding Back Clinical Data in a 510(k) Submission.** We also often tell clients to hold back clinical data in a 510(k) submission because FDA’s proclivity is to look at the submitted clinical data and automatically say it is not enough. This goes back to the psychological superiority discussed above. If you give clinical data to them in the original submission it will never be sufficient. If you submit it to them later as data responsive to a request for additional information, it will be additive data, viewed in a different light. Clients often say “Aren’t I required by law to submit that clinical data upfront in a submission?” The answer is “no.” By law, regulation and under the LB guidance a company is not obligated to provide more data than are needed and does not need to provide additional information that is not relevant to a SE determination. In addition, under LB principles “Clinical data are not required for most 510(k)s. Consequently, the Agency should clearly document the issue that warrants a request for

such data.” See, *The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry, at 5, October 2002*. A company needs to submit only that data which are necessary to demonstrate substantial equivalence and wait for FDA to document a need for clinical data.

**--FDA is Getting Better at Allowing Alternatives to RCTs.** Some reviewers and/or their supervisors seem to be getting better at considering requests for clinical data that are confirmatory of solid performance data, but are not from RCTs. They will consider alternatives to RCTs, but the data still need to be collected in manner which assures the data are meaningful and not biased. As mentioned earlier in this Client Alert, there is spotty evidence that LB principles are making their way into the ranks of management and even some review staff. For example, we have had some clients propose retrospective observational studies where data exist and the FDA is willingly to review it. The over-arching advice FDA provides to ensure such data constitutes “valid scientific evidence” is generically as follows:

- 1) The design of the collection effort is prospectively designed and retrospectively collected and attempts to address potential bias such as:
  - a) The sites are not cherry-picked, the rationale for site selection makes sense;
  - b) The patients chosen are not cherry-picked and there are reasonable inclusion and exclusion criteria; and
  - c) Collection from multiple sites and investigators helps here;
- 2) The design has success criteria/endpoints that are well-defined and agreed upon in advance of the commencement of data collection, e.g., in orthopedic devices-- pain, function, fusion and complications versus a comparator. This can be difficult when you have many different investigators involved and/or many different countries involved. FDA knows there will be artifacts and anomalies that will need to be explained;
- 3) Historical controls pulled from the literature can be acceptable to determine acceptable/normalized rates for endpoints, if the literature is clear and the data are somewhat poolable across authors/articles;
- 4) There are objective data that can be reviewed, such as radiographic data and x-rays for an orthopedic/spinal device;
- 5) Subjective scoring surveys are validated and/or standardized;
- 6) Can the data be audited; and
- 7) Others.

Arguments over biostatistical principles can still be a hang-up between industry experts and FDA. Sometimes FDA’s biostatistical experts have very good suggestions. At other times their position is either wrong or overly conservative and unaccepting of conventional measurements widely used within the expert community. Some of FDA’s in-house biostatistical experts are pragmatic; others get dogmatic and attempt to turn even the simplest clinical trial into an epidemiological exercise.

--**Conclusion.** The bottom line is that CDRH does seem to be slowly coming around to the idea of smaller confirmatory, non-RCT trials that are either prospective data collections or retrospective data. This too offers some hope to industry. If CDRH management can get review staff to be open-minded about the quality and quantity of data that are really needed to establish SE, then industry will survive and thrive and FDA will not be criticized for being overly risk averse. What industry needs is more predictability and, just as importantly, *reasonableness* in data requirements. That coupled with quicker, more definitive IDE decisions and SE determinations and the industry may recover from the last three very difficult years. There have been far too many companies that have gone out of business trying to survive the CDRH gauntlet to clearance. Others needlessly languish and limp out of FDA's tortuous grasp. Our hope is that investment capital will come off the sidelines and return to this once robust industry. But it will take an FDA that understands and eliminates, and does not just talk about, the impediments and obstacles it has created and perpetuates to make those wishes come true. This FDA needs to have metrics to measure the walk against the talk. In the process, patients will be protected with the right amount of data provided to substantiate performance and also will have timely access to important new therapies.

### **CALL US FOR HELP WITH YOUR REGULATORY & COMPLIANCE NEEDS**

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