DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

The 2nd Client Alert in Our Series on 510(k)s

Seven Quick Tips for Hitting the Mark on 510(k) Submissions

The second in a continuing series of Client Alerts on drafting and filing strategies for 510(k)s. We provide tips to ensure your 510(k) is an advocacy document which will garner the clearance you seek.

We have had a lot of success over the years in filing 510(k) submissions on behalf of clients. We have included a few a testimonials below. We are writing to share seven quick tips for filing 510(k)s. It is a simple synthesis of our expertise and experience drafting and filing 510(k) submissions for our clients. We can prosecute your 510(k) in a turnkey fashion or simply be part of the support team. You can ask us to be out front, behind the scenes, or as an advisor—so the FDA knows we are involved. Given our experience, which is measured collectively in decades of work negotiating and collaborating with the FDA, we know how to navigate the FDA process and how to

file 510(k)s that get you through the system faster. If we do not draft the 510(k), we can help you plan your submission and provide your team with strategic direction regarding predicate choices, making definitional arguments, laying out the 510(k) in a compelling and persuasive fashion, and making sure you comply with the RTA and eCopy guidelines. We can also help you think through your interface with the FDA—from early dialogue in responding to Additional Information Letters, to interactive submissions, to Submission Issues Meetings, to a full-blown Pre-Sub.

We frequently inherit 510(k)s that either were not drafted well or involve situations where the client was "stuck" in the 510(k) process with FDA. We know how to get you "unstuck." We are at FDA on average three times per month negotiating Pre-Sub meetings, 510(k)s, de novos, PMAs, and other matters on behalf of clients. We have earned the trust and respect of FDA and we advocate, when needed, for our clients so matters do not languish. We make sure FDA does not request inappropriate information or apply requirements irrelevant to a 510(k) determination. As much as FDA has improved in many areas, making timelines is not one of them and they can ask for information they want, not what they need or are entitled to, under the statutory and regulatory requirements of the 510(k) program.

We will make sure—through our input, editing and advice—that your 510(k) is the advocacy document it needs to be. Our 510(k) team and their bios are listed below and we are ready to help you.

DuVal & Associates' Seven Quick Tips for 510(k) Submissions

TIP 1: Begin with the end in mind—what marketers need to make your product differentiable and what product developers need to know

- Pick your predicates and intended use statements from your chosen predicate(s) wisely; be as close to the predicate(s) as possible—think "sameness"
- Make sure the developers understand how any changes to materials, technological approaches, the mechanism of action or functionality can impact FDA's review—think "sameness slightly progressed"
- Understand whether your technological characteristics raise different questions of safety and effectiveness—think "explainable sameness"

- Understand FDA's legitimate role and concerns—conduct an opposition analysis to anticipate FDA's concerns and questions.

TIP 2: *Remember the 510(k) is an advocacy document, not just an evidentiary document*

- Start with a statutory/regulatory/guidance analysis: construct your argument from the beginning—use FDA guidance as necessary using FDA's own words against them
- Don't "sell" your 510(k) to the FDA arguing how it meets an unmet clinical need, how it is superior or will change the practice of medicine —promote your product after clearance
- There are many opportunities throughout the document to succeed or derail your submission
- Think big picture: how can I make this device fit into the existing 510(k) framework
- It suggests to the FDA you know you what you are talking about and will hold them to the framework too

TIP 3: *Choose your predicates carefully and defend multiple predicates*

- FDA wants you to select a primary predicate—you are entitled to more
- FDA may suggest multiple predicates are inappropriate; split predicates are inappropriate
- Defend your choice using FDA's guidance documents

TIP 4: *When considering intended use statements understand the predicate landscape well and consider any additions carefully*

- When writing your intended use statement think "sameness"
- You can use an amalgam of predicates, but FDA likes a primary one
- FDA fights indication expansion: know how to advance this argument
- It is ironic that with a general intended use statement and without specifically stated indications, the device could be marketed for everything and yet nothing
- Understand FDA's guidance on "General/Specific Intended Use" ("levels of specificity" and "decision making" criteria) but do not be overly reliant on it, because FDA ignores it when it supports their position and uses it when it does
- It's easier to promote for use as a "tool" than ask FDA to allow you to focus in on one indication that FDA might consider a "treatment"

- Consider the full commercialization strategy when submitting—some indications must come in subsequent submissions; also think about claims from a reimbursement perspective, e.g., how will the indication you are seeking impact reimbursement?

TIP 5: *Consider the impact of your technological characteristics—the more differences, the more explanation and substantiation*

- Influence the device design to allow for profitable comparisons to the predicate—again, think "sameness"
- Remember any substantial changes require explanation and/or data
- Show the technological progression in the predicate family and that yours is not an outlier—think "sameness slightly progressed"
- Don't "sell" the superiority of your device to the Agency or that it meets an unmet clinical need or will change the practice of medicine

TIP 6: *Anticipate and address the different questions of safety and effectiveness raised by your technological differences*

- Identify and address them, because FDA will—superficially; make arguments that they are not "different" questions—think "explainable sameness"
- Use FDA's own Additional Information (AI) questions and guidance documents against them
- Don't forget to use "reference" devices to demonstrate FDA has seen this technology/questions before
- Provide data where needed to assure FDA you have been thorough
- Consider data needs carefully and whether you will need FDA's input in advance (i.e. Pre-Sub)

TIP 7: *Attend to the basics*

- Refusal-to-Accept Policy
- eCopy Policy
- Deadlines and communication
- Avoiding Pre-Subs (Q-Subs) where possible, but managing them correctly when needed

Here are testimonials from just a few clients.

“We’ve used DuVal & Associates to help us make five 510(k) submissions. What we like about them is their great relationship with FDA and their advocacy for us. They know how to work with the Agency and help communicate why our device belongs on the 510(k) path and then help us move it along expeditiously to clearance. They’ve taught us a 510(k) submission is more than cutting and pasting together data in a framework. It is an advocacy document where you tell your story about the elements of the 510(k) program so you don’t end up with a de novo or PMA. It’s also about giving FDA the right amount of data and pushing back diplomatically when the demands are too great. We have enjoyed our relationship with the firm, the practicality of their work and their responsiveness to our needs and passion for our success.” -Raul Brizuela, President and CEO, Argentum Medical

"As a Dutch company, Enraf-Nonius, sells its products in over 100 countries. Despite meeting all regulatory requirements in all those countries we still found it very difficult to get market approval for any of our class 2 devices in the USA. After several unsuccesful attempts to arrange this by doing everything ourselves from the Netherlands, one of our US contacts pointed us to DuVal & Associates. DuVal reviewed our technical files, helped us finalize the 510(k) documentation and dealt with all FDA-contacts. Getting a product approved is never a quick and easy process but together we managed to get our first product approved within 8 months. For us this was definite proof that we have found the right partners for any regulatory question in the USA." -Tom Doodkorte, Chief Marketing Officer, Enraf-Nonius

"I am very pleased with the guidance and FDA510(k) assistance provided by DuVal & Associates for our recent Class II 510(k) clearance. We (Ambient Clinical Analytics) brought one of the first Clinical Decision Support software solutions through the FDA's 510(k) process. In addition to submitting a software medical device that the FDA had little experience with, this was also the first regulatory experience for Ambient Clinical Analytics. We received clearance 4 months post submission, a remarkable achievement we couldn't have achieved without DuVal & Associates guidance and counsel from pre-submission education on the regulatory processes, the submission package creation and reviews, and their assistance with the fast path 3rd party review process. Post submission we were assigned a new FDA reviewer, reviewing a new software medical device. DuVal & Associates provided leadership and excellent counsel on how to most effectively move through a very challenging FDA review as effectively and quickly as possible -

resulting in a successful clearance for our product. I recommend DuVal & Associates to achieve the most effective and efficient path through the regulatory process." -Deb Sutherland, VP Software Development, Ambient Clinical Analytics

Here is our 510(k) team:

Mark DuVal is a former general counsel to 3M Pharmaceuticals, 3M Drug Delivery Systems and three medical device divisions before becoming FDA and compliance counsel at Medtronic. He started his law firm in 2002 has worked on 510(k)s for decades and has made his mark in helping clients strategize, draft, submit and, if necessary, attend Pre-Sub meetings and appeal 510(k)s.

Dave Teicher is biomedical engineer by training. He spent 11 years as an FDA investigator in both the Los Angeles and Minneapolis District Offices. He had 21 years in industry with approximately seven start-up and mid size companies holding various titles as director of regulatory, compliance and quality. Dave has been at DuVal & Associates for 10 years. He helps clients strategize, draft, submit and, if necessary, attend Pre-Sub meetings and appeal 510(k)s.

Amy Fowler worked in regulatory affairs and quality systems at 3M Medical Devices and 3M Pharmaceuticals over 15 years before adding a law degree to her BS in Chemistry. She also worked at Dentsply, Ecolab and RCRI, Inc. in regulatory affairs. Amy is now an Associate at DuVal & Associates where she helps clients strategize and draft submissions and also attend FDA meetings. She has many years of experience with CE Marking regulatory programs and other global regulatory submissions with a wide variety of companies, technologies, and therapeutic areas.

Beth Luoma is our newest associate and spent time at Medpace doing clinical research drafting protocols and monitoring clinical studies. Beth has been at DuVal & Associates since 2014. She too helps clients strategize, draft, submit and, if necessary, appeal 510(k)s.

All bios for our regulatory lawyers can be found at www.duvalfdalaw.com.

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CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture pharmaceuticals, medical devices, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups.

For more information, visit our website at www.duvalfdalaw.com or call today for a consult at 612.338.7170.