

DUVAL CLIENT ALERT

March 2010

In this DUVAL CLIENT ALERT, we announce the launch of our new website. We also introduce the Minnesota Medical Device Alliance and provide an overview of recent events which relate to the 510(k) Program.

NEW WEBSITE

We've recently created a new website for DuVal & Associates. Check it out at <http://www.duvalfdalaw.com/>. The new website contains a resources section along with firm news and upcoming events.

MINNESOTA MEDICAL DEVICE ALLIANCE

We've Started a Coalition Related to the 510(k) Program

As we all know, the 510(k) Program has been under siege for some time. Here is a quick overview of significant events to date related to the 510(k) Program:

- 2007-08:
 - Report on the 510(k) Program commissioned by the Food and Drug Administration Amendments Act of 2007 (FDAAA) and issued by the General Accounting Office (GAO).
 - Report subsequently misread and misused by those with an agenda to change the 510(k) Program.
- April 2009:
 - Whistleblowers from FDA write Congress and the Obama Administration claiming CDRH management overturns their scientific decisions and clears "unsafe" products.
 - Media describes the 510(k) Program as a "fast track" process, implying little data is provided and not enough FDA thought put into devices cleared by FDA.
- June 2009:
 - Congressman Waxman and Pallone hold a Congressional hearing with more planned.

- August 2009:
 - Center Director Dan Schultz resigns under pressure from Commissioner Hamburg over the 510(k) Program.
- September 2009:
 - FDA conducts an “internal” review on the ReGen clearance and issues a report calling for changes to the 510(k) Program.
 - Update: yesterday it was reported that an FDA advisory panel will reconsider ReGen’s clearance.
 - FDA asks the Institute of Medicine (IOM) to conduct an independent review of the 510(k) Program.
- October 2009:
 - Donna Bea Tillman, Director of the Office of Device Evaluation (ODE) within CDRH commissions an internal working group to fashion new clarifications/interpretations for the 510(k) Program for which CDRH will issue guidance documents.
- November 2009:
 - New Commissioner Hamburg states the 510(k) Program is “clearly troubled” and needs to be changed.
 - Venture investment in the medical device space nearly grinds to a halt.
- February 2010:
 - Meeting titled, “Strengthening the Center for Devices and Radiological Health’s 510(k) Review Process,” held by FDA.
 - Meeting expected to support the efforts of FDA’s internal working group.

 - Agency task force is scheduled to announce recommended policy changes in June.
 - Meeting presentations posted by FDA at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-N-0054>.
- March 2010:
 - Comments period for feedback on issues raised at February meeting extended to March 19.
 - For more information on submission of comments visit: <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-N-0054>.
 - Donna Bea Tillman resigns.

The problem is that the review of government 510(k) Program performance is being conducted by the government. Industry has largely been left on the sidelines. We need to participate in this process because the end product will have a huge impact on Minnesota’s medical device and investment communities. In consideration of this impact, DuVal & Associates recently founded the Minnesota Medical Device Alliance (MMDA) along with the law firm of Oppenheimer, Wolff & Donnelly LLP and the MedTech Resource Alliance. MMDA is focused on ensuring that the Minnesota medical device and venture communities have ongoing substantive input into FDA’s and Congress’ efforts to change the 510(k) Program. MMDA held a meeting last month

where the 510(k) Program was discussed. The meeting was well attended by medical device CEOs, the venture community, members of the Minnesota Congressional delegation and the press. As a follow up to the meeting, MMDA is working diligently with both the Minnesota Congressional delegation and FDA with the goal of making both aware of MMDA's concerns with the way the 510(k) Program is being administered today.

Here are a few links to press on MMDA:

MedCity News

Minnesota med tech on possible 510(k) overhaul: 'We're not gonna take it ...'
<http://www.medcitynews.com/2010/02/minnesota-med-tech-community-on-possible-510k-overhaul-were-not-gonna-take-it/>

Star Tribune

Med-tech group to discuss FDA's 510k process
http://www.startribune.com/business/84521802.html?elr=KArksLckD8EQDUoaE_yqyP4O:DW3ckUiD3aPc:_Yyc:aUUsZ

DuVal & Associates will keep you abreast of MMDA's progress. Stay tuned for updates.

CALL ON US FOR REGULATORY ASSISTANCE

DuVal & Associates was the first, and continues to be the only FDA-focused law firm without a west- or east-cost address. Every attorney at DuVal & Associates has worked in industry. We've been in your shoes. We understand your goals and challenges. Our efficient and responsive attorneys can counsel you on a range of topics including Submissions, Promotion, Compliance, Clinical Research and Manufacturing. Our firm has put together compliance programs and training covering company code of conduct, AdvaMed Code, Anti-kickback Statute, False Claims Act, advertising and promotion under the Food, Drug and Cosmetic Act, and HIPAA for nearly 100 companies. We can help your organization understand not only what it *cannot* do, but what it *can* do. In sum, our real-world experience can help you accomplish your goals in an appropriately aggressive yet compliant fashion.

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