

Cerulean Interviewed in "**The Gray Sheet**" on
Medical Device Silent RecallsCerulean Associates LLC
<http://www.ceruleanllc.com>

FOR IMMEDIATE RELEASE

March 5, 2008 – Williamsburg, Va. – John Avellanet, Cerulean's Managing Director, was interviewed for a recent article for "**The Gray Sheet**" entitled "FDA on the Lookout for Potential Recalls Masked as Service Requests" (March 3, 2008).

The FDA is concerned about growing problems with medical device software. Mr. Avellanet noted that "no software that's complicated is ever really perfect" and went on to discuss that hidden or "silent" recalls are more common the more complex the medical device.

When it comes to determining if a complex medical device needs to be recalled, Mr. Avellanet explained that if a firm is making a maintenance call or a fix to all its devices going forward, then the question is whether or not that decision is based on risk to the patient or end-user (like a healthcare provider) of the device. "If you are making it because of risk," said Mr. Avellanet, "then you really should be classifying it as a recall – not a service request, not a maintenance request, not a maintenance update."

Mr. Avellanet was interviewed on FDA enforcement trends and targets when it comes to medical device manufacturers. He will be giving a talk on FDA enforcement trends and targets March 18th for *FDA Expert Briefings* (www.expertbriefings.com).

Mr. Avellanet is the co-founder and principal consultant for Cerulean Associates LLC, the publisher of the monthly executive newsletter *SMARTERCOMPLIANCE*[™], and the compliance columnist for the international *Journal of Commercial Biotechnology*. He serves on the boards of a number of industry associations.

Cerulean Associates LLC is a small, private compliance consulting company that helps executives achieve cost-effective lean compliance, quality by design, intellectual property security, and faster time to market. On the web at www.ceruleanllc.com.

###

For more information, contact:

John Avellanet
Managing Director
Cerulean Associates LLC
PO Box 498
Williamsburg, VA 23187 USA
+1.757.645.2864
info@ceruleanllc.com