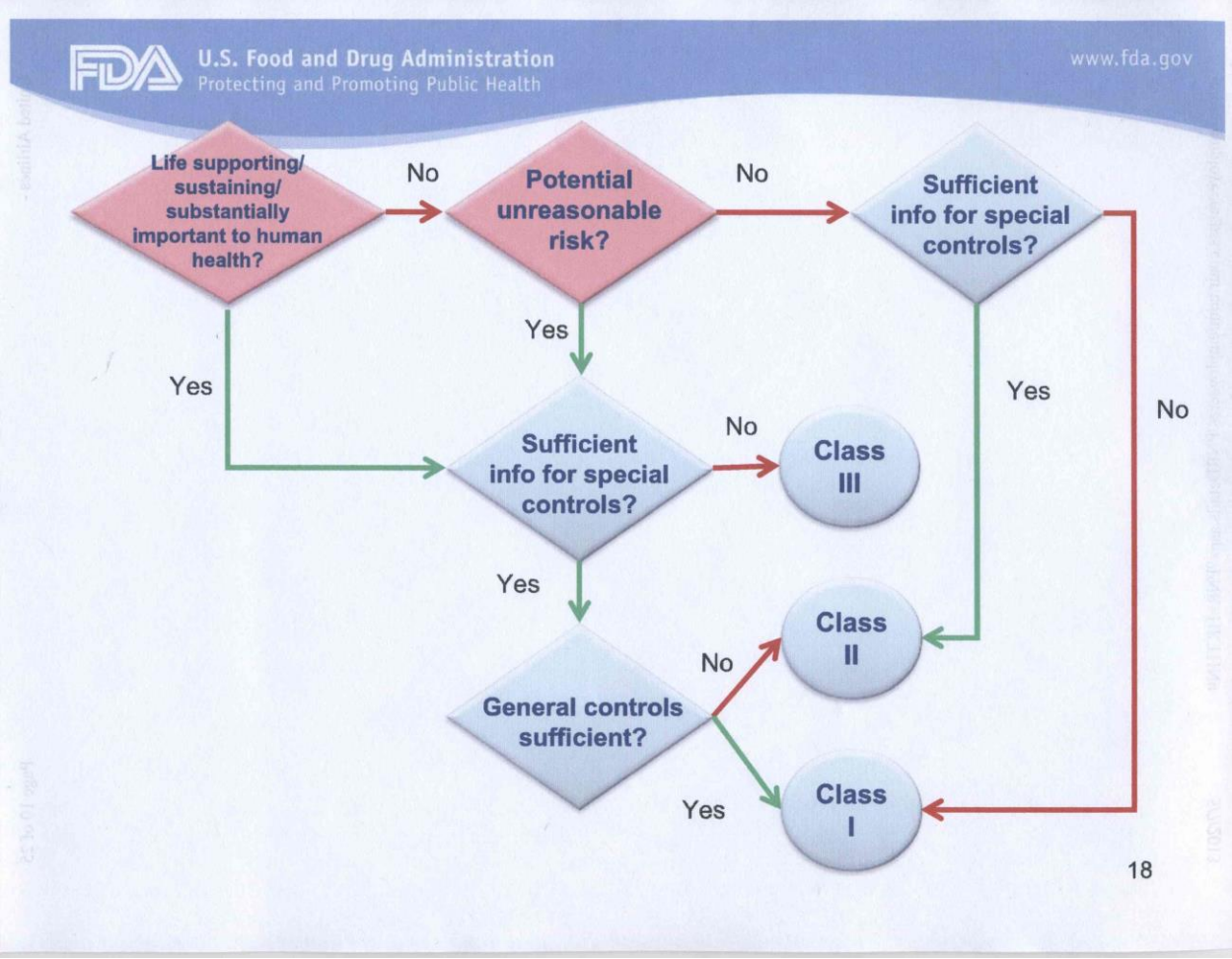
CDRH representatives have instructed advisory Panels about the basics of medical device classification many times over the years. Their slide shows also include logic diagrams to illustrate the process. For example, the diagram shown at the Orthopaedic and Rehabilitation Devices Panel meeting on May 21, 2013 appears below:



When I perused the diagram after the meeting, it didn't seem right that a device could be in Class I unless the question "Are general controls sufficient to provide reasonable assurance that the device is safe and effective?" is answered "Yes." I concluded that the second path – the red line at the right side of the diagram could not be correct. It seemed quite illogical that a device could be in Class II if there is sufficient information for special controls to provide reasonable assurance that a device is safe and effective, but in Class I if there is not sufficient information.

I was so convinced that I have made a nuisance of myself, reporting this alleged error to various FDA officials, with no good outcome. Mostly I was ignored. Nobody took the time to inform me that I was mistaken.

On December 10, I belatedly researched the definition of Class I and found that both pathways to Class I are valid. I WAS WRONG AND REGRET MAKING SUCH AN ISSUE ABOUT THIS MATTER.