

## 5 TIPS FOR A COMPETITIVE REGULATORY STRATEGY

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If you want to gain a competitive edge, having a competitive regulatory strategy is one way to go about it. Here are a few tips for devising one:

1. Know the regulatory pathways very well. Develop an “executive summary,” which helps you to measure the pros and cons, the time and effort involved, the cost and the likelihood of the FDA approval.
2. Understand that the “path of least resistance” (ie. the 510(k)) isn’t always the most beneficial to your company from a competitive standpoint. If you take a more complex route such as the PMA, you are making it more difficult for your competition at the same time.
3. Consider how you might be able to influence regulation, particularly if you have a new and novel product that has never been done before. The FDA creates its guidances based on the first few products submitted in that area. This means you could try to get a competitive advantage by creating a testing methodology that is favorable to your own product, but difficult for competitors to use.
4. Be prepared to explore different avenues. For example, you can read between the lines of what a regulation does and doesn’t say. Under an HDE (humanitarian device exemption), you’re only allowed to sell 4000 devices per year, however you could slice and dice populations by going for particular indicators. Once approved you could then apply for a label expansion, which tends to be much easier than initially bringing a product to market.
5. Know the exceptions to the rules. Like the example in #4, there are often ways around the rules that are perfectly legal and don’t compromise safety or efficacy.