How To Create a Class II SaMD Regulatory Strategy

A winning regulatory strategy for SaMD has five fundamental elements which reflect the key components of your future submission:

1. **The Right Regulation and Predicate**
2. **Risk Management**
3. **Software & Cybersecurity Testing**
4. **Human Factors & Usability Testing**
5. **Clinical Validation Testing**

In this "How To" guide, I have listed a series of questions I would typically ask a client when creating a regulatory strategy with them along with notes throughout to help guide you in the right direction. Here is **STEP 1: THE RIGHT REGULATION & PREDICATE**. Happy strategy formulating!

STEP 1: THE RIGHT REGULATION & PREDICATE

Note: This first step will shape the core of your regulatory strategy and future submission. Subsequent steps are a direct reflection of the regulation and predicate selected.

- Have you looked through FDA's searchable databases, specifically "Product Classification", "De Novo", and "Premarket Notifications (510(k)s)" to find any potentially applicable regulations/product codes?
  *Note: a **regulation number** is a specific reference to the Code of Federal Regulations (CFR) that defines a generic type of device. It uses the format: 21 (title for Food and Drugs) + CFR + 870 (device panel) + XXXX (specific device type), for example 21 CFR 870.5801 is for Computerized Behavioral Therapy Device for Substance Use Disorders; a **product code** is a three-letter code assigned by FDA for internal tracking and review purposes to group similar devices. Yes, a single regulation number can have multiple product codes! For example, 21 CFR 870.2210 "Adjunctive Predictive Cardiovascular Indicator has both QAQ and QNL. This is an interesting precedent that we can learn from! The definition of this regulation is quite broad while the product codes further define the technology.*
- Read the regulation **definition** & **description** which define intended use and sometimes even form-factor. Does your product generally meet those criteria?
  Note: 21 CFR 870.2210 is an interesting precedent (or prior decision by FDA) that we can learn from! The definition of this regulation is quite broad while the product codes further define the technology.

- What competitor products have been released on the market in the last 5 years? Let's go find the 510(k) Summary for each of those products.
  Note: a 510(k) summary is a document drafted by the medical device manufacturer that describes the device, contains a table that compares the device to their selected predicate, and summarizes the testing completed to support the submission. FDA makes the 510(k) summary publicly available in their Premarket Notifications (510(k)s) database.
- Of the products released on the market within the last 5 years, which is most like your device?
  Note: You can choose a later predicate, but it is advised to go back no more than 10 years. This is because FDA's understanding of technology and the testing needed to mitigate its risk profile is constantly evolving as they learn more from real world use.
  Note: Choosing multiple predicates can be a great strategy when you want to leverage precedents set by prior FDA clearances. Precedents can be very handy when your device and the predicate have some distinct differences that can be justified by references additional predicates and the associated risk profiles.
- We need to craft a **substantial equivalence[1] argument** that is based on comparing intended use, indications for use and technological characteristics. Here are some general questions to ask as you compare intended use, indications for use, and technological characteristics:
  - What could go wrong either with the device or how the device is used?
    Note: This helps us compare risk profiles between your device and the predicate device.
  - As I compare these products would I be asking the same questions about how the product works and how it is tested if I were reviewing the submission?

  Note: Substantial equivalence does not mean identical. Substantial equivalence means that your device is similar enough to the predicate such that any testing you would perform to prove out device capabilities are the same,
- Can't find the right regulation and predicate fit? Are your competitors only marketing products in Europe? We might be looking at a **De Novo** submission because your product is likely first-of-a-kind where there are no legally marketed predicates.

[1] The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]