Product Profile: Devices

A product profile provides a structure for the scientific, technical, clinical, and market information that is required to achieve a desired commercial outcome. It provides all stakeholders with a clear vision of the product objectives and helps guide research and development decisions. It is a dynamic strategic document that should be reviewed throughout the development process. *It identifies the aspirational and minimal product attributes and claims that are key indicators for success. These will be the thresholds that you will use to determine if your product's testing and metrics are acceptable.*

While filling out this form, consider how the device compares to and improves upon its competitor.

Product Name	
Product Description Detailed description of the product including its parts/components, how the device functions, if it will be used independently or in combination with other devices and if software is involved	
Unmet Clinical Need Description of the unmet clinical need and how the product will change medical practice. Consider how the clinical need is currently addressed.	
Intended Use Specific indications, characteristics of the target population and device user, where the device will be used (in-patient, out-patient, home)	
Freedom to Operate and IP Position Consider the novelty of your technology and patent eligibility. Describe the extent of interactions with the technology transfer office. Please include a list of the various types of IP filed or granted (including patent application number, issued patent number, title, status and date) and the major types of claims (e.g., composition of matter claims, use claims, process of manufacturing claims). Also list the IP events anticipated during development.	
Manufacturability	

The ease and cost of manufacturing including: availability and cost of starting material; scalability of manufacturing process; total yield from readily available starting material; and competitor's cost.		
Required Reference Standards ISO standards that will be referenced		
Comparative Devices Predicate device(s) that will be used for comparison		
Device Functional Specifications Function of the device and its components, focusing on the operational capabilities and design features needed to achieve the functions. Include dosage & administration if applicable. *This should **NOT** be the observed measurements of the device. This information should list the target and minimal criteria the device and its components must meet to be considered successful. The criteria will guide the decision making process and provide you with a checklist of metrics your device must meet.*	***Target***	***Competitor***
Human Factor Considerations Contraindications and design considerations to ensure safe and effective use by the target population and device users	***Target***	***Competitor***
Dimensional Requirements Dimensional requirements necessary to fabricate the device *This should **NOT** be the observed measurements of the device. This information should list the target and minimal criteria the device and its components must meet to be considered successful. The criteria will guide the decision making process and provide you with a checklist of metrics your device must meet.*	***Target***	***Competitor***

Material Requirements Material requirements necessary to fabricate the device. Consider safety, shelf life, functionality, etc. *This information should list the target and minimal material criteria the device and its components must meet to be considered successful. The criteria will guide the decision making process and provide you with a checklist of metrics your device must meet.*	***Target***		***Competitor***
Performance Requirements How much or how well the device must perform, including issues such as speed, strength, response times, accuracy, limits of operation, etc. Include any performance testing that will be conducted prior to entering clinical testing. *This should **NOT** be the observed measurements of the device. This information should list the target and minimal criteria the device and its components must meet to be considered successful. The criteria will guide the decision making process and provide you with a checklist of metrics your device must meet.*	***Optimistic***	***Minimal***	***Competitor***
Environmental Issues Related to Design Design considerations that account for the range of environments and applicable environmental conditions in which the device might be used (location of intended use, transportability, contaminants, storage and shelf life, etc.)			
Device Safety Safety profile and requirements to be met (e.g. non-clinical toxicology). Include testing that will be conducted prior to entering clinical testing. *This should **NOT** be the observed measurements of the device. This information should list the target and minimal criteria the device must meet to be*	***Target***		***Competitor***

considered successful. The criteria will guide the decision making process and provide you with a checklist of metrics your device must meet.		
Packaging Packaging necessary for the device. Consider if it is intended for multi or single use; home or hospital setting; the expected shelf life, etc. *Packaging of comparative diagnostic should be referenced.*		
Labeling Labeling necessary for the device including labeling to identify components or measurements *Labeling of comparative diagnostic should be referenced.*		
Regulatory Requirements Regulatory path to pursue [510(K), PMA, or De Novo] in consideration of marketing strategy [national, international or both]		
Preclinical Testing Additional testing (e.g. efficacy) that will be performed prior to entering clinical testing, including bench, in vivo, computer simulations, sterility, biocompatibility, robustness, etc. Consider how you will scale-up for testing.		
Clinical Studies Study model, testing, and clinical data necessary to support use and for FDA clearance. Consider competitive position and marketing strategy.		