User Needs Draft: Evaluation Rubric				
Disease State Fundamentals (20%)	**Excellent (typically "A" work)**	**Good (typically "B" work)**	**Fair (typically "C" work)**	**Needs Improvement (typically "D" work)**
Content: - Definition of clinical need (i.e. disease state) - Description of scale/scope of disease (i.e. epidemiology) - Summary of patient's journey and typical treatments/outcomes - What drug or growth factors are most promising to improve patient outcomes	- **Disease state** is sufficiently defined for an educated outsider (e.g. not a clinician) to understand the need - Key facts about the **disease and its treatment**, including those related to its breadth and limitations, are presented - The **pathway/experience of a patient**, from the initial onset through diagnosis and treatment options, is well defined - **Drugs or Growth Factors**, and the **healing/recovery pathway** is described to highlight options for drug eluting products - Vocabulary is used which reflects a comfort with the clinical space - Citations are ample and appropriate	A few **minor** issues in categories such as the below:	Several **significant** issues in categories such as the below:	**Missing** key information and/or **substantial issues** in categories such as the below:
		- Disease state is lacking in detail and/or does not convincingly elucidate the need - Sufficient facts and/or citations are not presented to characterize how the disease is seen from the clinical/epidemiological perspective, experienced from the patient perspective, and encountered from the clinicians' perspective - The wound healing and problem pathways are not described, and it is unclear what our future product could elute - Vocabulary demonstrates a general lack of comfort with the relevant terminology - Citations lacking or in inappropriate format		
Existing Solutions & Regulation (20%)				
Content: - Description of product(s) which are either currently used or fulfill a similar function in another field - Visuals of the products - Explanation of the products' shortcomings - Analysis of the gaps and opportunities for an innovation - Discussion of the suitability of any product as substantially equivalent (ie. predicate device or not) - Discussion of regulatory path, including device classification	- Products highlighted capture the **spectrum of products / approaches** available - Existing products / approaches are **well described** including what they are, how they work, their **strengths/weaknesses** - Connections are established between existing products and need statement via the **identification of shortcomings** - **Visuals** of the products effectively illustrate **important aspects** of said products - Products highlighted are accurately described as a **predicate or not a predicate** device. - Categorization of your future design (**biologic, drug, device, or combination**), device classification (**I, II, or III**) and regulatory path (**510K, exempt, de novo, or PMA**) are correct, clear, and thorough. - Citations are ample and appropriate	A few **minor** issues in categories such as the below:	Several **significant** issues in categories such as the below:	**Missing** key information and/or **substantial issues** in categories such as the below:
		- Clarity and/or a few missing details of the product(s), how they work, their strengths, and/or shortcomings - Connection to the problem statement is a little unclear - Products don't fully represent the most relevant solutions in and/or outside of the field - Analysis of the gaps/opportunities are not fully convincing and/or evidence-based - Incorrect conclusions on substantial equivalence or lack of details in regulatory pathways - Citations lacking or in inappropriate format		
Stakeholder Analysis (20%)				
Content: - Written summaries of positive and negative impact for each stakeholder identified, using both cycle of care and the flow of money analysis - Graphical represenation of your findings (e.g. flowchart with stakeholders as nodes and indicators of positive/negative effects.)	- Stakeholders from **both** cycle of care and flow of money analyses are presented are well-considered, leaving no major gaps - Analysis is balanced, conveying accurately how parties would **benefit or not** from the meeting of the communicated need - **Chart(s)** is presented which clearly indicates the **connections** between stakeholders and provides a visualization of their effect (e.g. by arrows, with + or -) - Citations are ample and appropriate	A few **minor** issues in categories such as the below:	Several **significant** issues in categories such as the below:	**Missing** key information and/or **substantial issues** in categories such as the below:
		- Diagram either missing entirely or insufficient in extent - Claims about stakeholders present without sufficient justification/rationale - Analysis indicates overwhelming negative reaction to need being addressed without ample discussion - Analysis oversimplifies (e.g. takes "too rosy of a view") the reactions of stakeholders - Citations lacking or in inappropriate format		
Market Analysis (20%)				
Content: - Analyze the properties (size, growth, and dynamics) of the market (TAM) --- Include a graphic of the market dynamics - Identify the target market (Population), separating into Total Available Market, Serviceable Available Market, and Serviceable Obtainable Market (TAM, SAM, SOM) --- Include a graphic of TAM, SAM, and SOM - Describe who you expect to compete with for market share, as justification for your SOM from the identified SAM	- TAM/SAM/SOM are justified with **written rationale** for their calculations - **Graphics** are appropriately presented which highlight both the **general dynamics** of the TAM and also the **breakdown of the TAM/SAM/SOM** - **Major players** are identified along with **example offerings** (linked to existing solution analysis above) and a breakdown of the relative dominance/parity in the market - Justifications for split from Total to Available to Obtainable are reasonable and based on **team's choice** of selling to or competing with major players - Citations are ample and appropriate	A few **minor** issues in categories such as the below:	Several **significant** issues in categories such as the below:	**Missing** key information and/or **substantial issues** in categories such as the below:
		- Graphics missing entirely or do not effectively communicate market dynamics - Approach to TAM/SAM/SOM lacking in justification or quantification - Missing market players and/or lacking information about their relative share of the market - Errors or missing expansion on the suitability of the market for a product with relation to the key players and future dynamics - Citations lacking or in inappropriate format		
Summary (20%)				
Content: - Who is impacted, magnitude of the problem (Population) - Description of the current situation and difficulties (Problem) - Summary of existing solutions and their limitations (Outcome) - Need statement - Scope/constraints imposed by VMO	- An overall summary that supports the Problem, Population, and Outcome to be seen in the Need Statement, which effectively establishes the design space --- summary **quickly** states the Problem, who is impacted/stakes of the Problem, and is backed by appropriate statistics, pulled from earlier sections of the report - Need statement is **concise, well-scoped, and actionable** --- Superseding needs, if present, are noted along with a discussion of the likelihood that they will be addressed by other parties - After the initial needs are defined, the scope is defined considering the constraints from VMO (bypass graft or hip implant)	A few **minor** issues in categories such as the below:	Several **significant** issues in categories such as the below:	**Missing** key information and/or **substantial issues** in categories such as the below:
		- Lacking clarity, accuracy, and/or completeness of the problem description, existing solutions summary, or need - Impact/magnitude is not quantified but is qualitatively described (or not described at all) - Problem narrative and/or framing is somewhat unconvincing, missing some supporting evidence from the four categories presented in class - Need statement is not concise and/or **introduces new information not supported by the problem** **- Need statement is solution biased** - Scope does not match what VMO has asked the team to focus on, without compelling argument to do so		
REMINDER: Logistics (up to 10% deduction if not correct)				
Font, font size, spacing, margins, page numbers, and word limits	See assignment description	A few **minor** issues	Several **significant** issues	**Missing** and/or **substantial issues**