

Item #	User Needs Intended Uses	Design Inputs (Technical Requirement)	Acceptance Criteria		Design Outputs	Design Verification (Outputs = Inputs)	Design Validation (User Needs Met)
			Ideal/Goal	Limit			
1.0	Customer Requirements (e.g. Functional)						
1.1							
1.2							
1.3							
2.0	Product Performance Requirements (e.g.Mechanical)						
2.1							
2.2							
2.3							
3.0	Biocompatibility Requirements						
3.1							
3.2							
3.3							
4.0	Regulatory Requirements						
4.1							
4.2							
4.3							
5.0	Interfaces with Other Systems						
5.1							
5.2							
5.3							
6.0	Other						
6.1							
6.2							
6.3							