Device Categories			Biological Tests											
			Short-term								Long-term			
Body Contact		Contact Duration A = Transient (<5 minutes) B = Short-term (5 minutes-29 days) C = Long-term (>30 days)	Irritation Tests	Sensitization Assay	Cytotoxicity	Acute Systemic Toxicity	Hemocompatibility/Hemolysis	Pyrogenicity (material-mediated)	Implantation Tests	Mutagenicity (Genotoxicity)	Subchronic Toxicity	Chronic Toxicity	Carcinogenesis Bioassay
External Devices	Intact Surface	A	*	*	*								
		B	*	*	*								
		C	*	*	*	*							
	Breached or Compromised Surface	A	*	*	*	*	*						
		B	*	*	*	*	*				*		
		C	*	*	*	*	*		*	*	*	*	
Externally Communicating Devices	Intact Natural Channels	A	*	*	*	*	*	*	*				
		B	*	*	*	*	*	*	*	*	*		
		C	*	*	*	*	*	*	*	*	*	*	*
	Blood Path Indirect	A	*	*	*	*	*	*	*	*			
		B	*	*	*	*	*	*	*	*	*		
		C	*	*	*	*	*	*	*	*	*	*	*
	Blood Path Direct	A	*	*	*	*	*	*	*	*			
		B	*	*	*	*	*	*	*	*	*		
		C	*	*	*	*	*	*	*	*	*	*	*
Internal Devices	Bone	A	*	*	*	*	*	*	*	*			
		B	*	*	*	*	*	*	*	*	*		
		C	*	*	*	*	*	*	*	*	*	*	*
	Tissue and Tissue Fluids	A	*	*	*	*	*	*	*	*			
		B	*	*	*	*	*	*	*	*	*		
		C	*	*	*	*	*	*	*	*	*	*	*
	Blood	A	*	*	*	*	*	*	*	*			
		B	*	*	*	*	*	*	*	*	*		
		C	*	*	*	*	*	*	*	*	*	*	*

Table A1

Medical device categorization by:			Endpoints of Biological Evaluation															
Nature of body contact		Contact Duration	Physical and/or chemical information	Cytotoxicity	Irritation or intracutaneous reactivity	Sensitization	Material Mediated pyrogenicity	Acute Systemic Toxicity	Sub acute systemic toxicity	Sub chronic systemic toxicity	Chronic systemic toxicity	Implantation effects	Hemocompatibility	Genotoxicity	Carcinogenicity	Reproductive/ developmental toxicity	Degradation
Category	Contact	A – **limited** (≤24 h) **B – prolonged** (>24 h to 30 d) **C – Long term** (>30 d)															
Surface medical device	Intact skin	A	X	E	E	E											
		B	X	E	E	E											
		C	X	E	E	E											
	Mucosal Membrane	A	X	E	E	E											
		B	X	E	E	E		E	E			E					
		C	X	E	E	E		E	E	E	E	E		E			
	Breached or compromised surface	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E					
		C	X	E	E	E	E	E	E	E	E	E		E	E		
Externally communicating medical device	Blood path, indirect	A	X	E	E	E	E	E					E				
		B	X	E	E	E	E	E	E				E				
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
	Tissue/bone/dentin	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Circulating blood	A	X	E	E	E	E	E					E	Ej			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		
Implant medical device	Tissue/bone	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		





Endpoints of Biological Evaluation

Medical device categorization by:			Pre-Screen		Local Effects		Immune Toxicity	Systemic Effects					Genotoxicity			Special Cases	
Nature of body contact		Contact Duration	Physical and/or chemical information	Cytotoxicity	Irritation or intracutaneous reactivity	Implantation effects (Local Tissue Response)	Sensitization	Material Mediated pyrogenicity	Acute Systemic Toxicity	Sub acute systemic toxicity	Sub chronic systemic toxicity	Chronic systemic toxicity	Genotoxicity	Carcinogenicity	Reproductive/ developmental toxicity	Hemocompatibility	Degradation
Category	Contact	A – **limited** (≤24 h) **B – prolonged** (>24 h to 30 d) **C – Long term** (>30 d)															
Surface medical device	Intact skin	A	X	E	E		E								?		?
		B	X	E	E		E								?		?
		C	X	E	E		E								?		?
	Mucosal Membrane	A	X	E	E		E								?		?
		B	X	E	E	E	E		E	E					?		?
		C	X	E	E	E	E		E	E	E	E	E		?		?
	Breached or compromised surface	A	X	E	E		E	E	E						?		?
		B	X	E	E	E	E	E	E	E					?		?
		C	X	E	E	E	E	E	E	E	E	E	E	E	?		?
Externally communicating medical device	Blood path, indirect	A	X	E	E		E	E	E	E					?	E	?
		B	X	E	E		E	E	E	E	E	E			?	E	?
		C	X	E	E	E	E	E	E	E	E	E	E	E	?	E	?
	Tissue/bone/ dentin	A	X	E	E		E	E	E	E					?		?
		B	X	E	E	E	E	E	E	E	E	E	E		?		?
		C	X	E	E	E	E	E	E	E	E	E	E	E	?		?
	Circulating blood	A	X	E	E		E	E	E	E			Ej		?	E	?
		B	X	E	E	E	E	E	E	E	E	E	E		?	E	?
		C	X	E	E	E	E	E	E	E	E	E	E	E	?	E	?
Implant medical device	Tissue/bone	A	X	E	E		E	E	E	E					?		?
		B	X	E	E	E	E	E	E	E	E	E	E		?		?
		C	X	E	E	E	E	E	E	E	E	E	E	E	?		?
	Circulating Blood	A	X	E	E	E	E	E	E	E			E		?	E	?
		B	X	E	E	E	E	E	E	E	E	E	E		?	E	?
		C	X	E	E	E	E	E	E	E	E	E	E	E	?	E	?