

BIOCOMPATABILITY TESTING



Device category		Initial Evaluation									Supplemental evaluation	
	Body Contact	Contact Duration	Cytotoxicity	Sensitization	Irritation or Intra cutaneous Reactivi	Systemic toxicity (acute)/ Pyrogenicity	Subchronic toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic toxicity	Carcinogenicity
Surface Device	Skin	A										
		B										
		C										
	Mucosal membrane	A										
		B										
		C										
	Breached / Compromised Surface	A										
		B										
		C										
External Communicating Devices	Blood path indirect	A										
		B										
		C										
	Tissue / bone dentin communicating	A										
		B										
		C										
	Circulating Blood	A										
		B										
		C										
Implant Devices	Bone issue	A										
		B										
		C										
	Blood	A										
		B										
		C										
As per MDD - A = Limited (<_ 24 Hours) B = Prolonged (24 Hours - 30 Days) C = Permanent (>30 Days)												
As per USFDA - A = Limited exposure B = Prolonged exposure (24 hours - 30 days) C = Permanent contact(>30 days)												

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