

Biocompatibility/Safety Evaluation Guidelines for US Submissions

ISO and FDA Test Selection Chart

- A Limited Exposure (< 24 hours)
- B Prolonged Exposure (> 24 hours to 30 days)
- C Permanent Exposure (> 30 days)
- ◆ ISO and FDA Evaluation Tests for Consideration
- ◇ Additional Tests for FDA

Device Categories		Biological Effects Initial Evaluation							Biological Tests Supplemental Evaluation				
Body Contact	Contact Duration	Cytotoxicity	Sensitization	Irritation / Intracutaneous Reactivity	Acute Systemic Toxicity	Sub-Chronic/Chronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductivity / Developmental Toxicity	Biodegradation
Surface Devices													
Skin	A	◆	◆	◆									
	B	◆	◆	◆									
	C	◆	◆	◆									
Mucosal membranes	A	◆	◆	◆									
	B	◆	◆	◆	◇	◇		◇					
	C	◆	◆	◆	◇	◆	◆	◇		◇			
Breached/ compromised surfaces	A	◆	◆	◆	◇							◇	
	B	◆	◆	◆	◇	◇		◇					
	C	◆	◆	◆	◇	◆	◆	◇				◇	
External Communicating Devices													
Blood path, indirect	A	◆	◆	◆	◆				◆				
	B	◆	◆	◆	◆	◇			◆				
	C	◆	◆	◇	◆	◆	◆	◇	◆	◆	◆		
Tissues/bones/dentin	A	◆	◆	◆	◇								
	B	◆	◆	◇	◇	◇	◆	◆					
	C	◆	◆	◇	◇	◇	◆	◆		◇	◆		
Circulating blood	A	◆	◆	◆	◆				◆				
	B	◆	◆	◆	◆	◇	◆	◇	◆				
	C	◆	◆	◆	◆	◆	◆	◇	◆	◆	◆		
Implant Devices													
Tissues/bones	A	◆	◆	◆	◇								
	B	◆	◆	◇	◇	◇	◆	◆					
	C	◆	◆	◇	◇	◇	◆	◆		◆	◆		
Blood	A	◆	◆	◆	◆				◆				
	B	◆	◆	◆	◆	◇	◆	◆	◆				
	C	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆		