

IRIS – Initial Risk Assessment & Data Entry Checklist

DOCUMENT 15

Device Description:	Hip prosthesis				
Date Assessed:	20.5.11	Assessed By:	[REDACTED]		
Sample Requested:	<input type="checkbox"/> YES <input type="checkbox"/> NO	Sample Received:	<input type="checkbox"/> YES <input type="checkbox"/> NO	Received From:	<input type="checkbox"/> Reporter <input type="checkbox"/> Other
				Device Type:	<input type="checkbox"/> Sterile <input type="checkbox"/> Reusable <input checked="" type="checkbox"/> Single Use
Classification:	<input type="checkbox"/> Urgent (48hrs) <input checked="" type="checkbox"/> Expedite (5days) <input type="checkbox"/> Routine (10days) <input type="checkbox"/> Not Investigated				
If Not Investigated:	Cause: Result: Recommendation:				
Initial Recommendation:	<input checked="" type="checkbox"/> Investigate (to IRIS Meeting) <input type="checkbox"/> Information Only <input type="checkbox"/> Refer to Surveillance				
Type of Incident <small>(tick more than one if necessary)</small>	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <input type="checkbox"/> Advertising <input type="checkbox"/> Biocompatibility <input type="checkbox"/> Contamination <input type="checkbox"/> Diagnostic Inaccuracy <input type="checkbox"/> Electrical </div> <div style="width: 30%;"> <input type="checkbox"/> Fails TGO / Standard <input type="checkbox"/> Labelling/Product Info <input type="checkbox"/> Material / Formulation <input checked="" type="checkbox"/> Mechanical <input type="checkbox"/> Packaging </div> <div style="width: 30%;"> <input type="checkbox"/> Product Mix Up <input type="checkbox"/> Software <input type="checkbox"/> Supply of Unlisted Device <input type="checkbox"/> Other </div> </div>				
Outcome of Incident <small>(tick one only for each criteria)</small>	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> Potential Outcome <input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> Temporary Injury <input type="checkbox"/> No Injury </div> <div style="width: 30%;"> Actual Outcome <input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> Temporary / Minor <input type="checkbox"/> No Injury </div> <div style="width: 30%;"> Injured Party <input checked="" type="checkbox"/> Patient <input type="checkbox"/> Operator <input type="checkbox"/> Not Applicable </div> </div>				
Reporter Type <small>(Source Category)</small>	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> Government Agency <input type="checkbox"/> Consumer Affairs <input type="checkbox"/> Coroner <input type="checkbox"/> TGA - Recalls <input type="checkbox"/> TGA - Labs <input type="checkbox"/> TGA - GMP <input type="checkbox"/> TGA - CAB <input type="checkbox"/> TGA - Surveillance </div> <div style="width: 30%;"> Paramedical <input type="checkbox"/> Ambulance <input type="checkbox"/> Dentist <input type="checkbox"/> Pharmacist <input type="checkbox"/> Physiotherapist <input type="checkbox"/> Radiographer <input type="checkbox"/> Rehabilitation <input type="checkbox"/> Other </div> <div style="width: 30%;"> Technical <input type="checkbox"/> Biomed Engineer <input type="checkbox"/> Biomed Technician <input type="checkbox"/> Clinical Technician <input type="checkbox"/> Hospital Engineer <input type="checkbox"/> Medical Physicist </div> </div>				
Risk Analysis <small>(tick one only for each criteria)</small>	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> Other <input type="checkbox"/> Blood Bank <input type="checkbox"/> Competitor <input type="checkbox"/> Hospital Supply Service <input checked="" type="checkbox"/> Patient / User <input type="checkbox"/> Sponsor <input type="checkbox"/> Other </div> <div style="width: 30%;"> Overseas Advice <input type="checkbox"/> ECRI <input type="checkbox"/> EU Vigilance <input type="checkbox"/> FDA (USA) <input type="checkbox"/> MDA (UK) <input type="checkbox"/> MDB (Canada) <input type="checkbox"/> Other </div> <div style="width: 30%;"> DIR #: 23483 Trim File #: 2011/007957 </div> </div>				
	<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> Frequency <input type="checkbox"/> Frequently <input type="checkbox"/> Sometimes <input checked="" type="checkbox"/> Rarely <input type="checkbox"/> Unlikely </div> <div style="width: 30%;"> Severity <input type="checkbox"/> Life Threatening <input checked="" type="checkbox"/> Serious <input type="checkbox"/> Minor <input type="checkbox"/> Nil </div> <div style="width: 30%;"> Detectable <input checked="" type="checkbox"/> Likely <input type="checkbox"/> Occasionally <input type="checkbox"/> Rarely <input type="checkbox"/> Unlikely </div> </div>				