

Device Description:	HIP Prosthesis						
Date Assessed:	16.2.10		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 type="checkbox"/> Expedite (5days)		<input checked="" 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 (tick more than one if necessary)	<input type="checkbox"/> Advertising <input type="checkbox"/> Biocompatibility <input type="checkbox"/> Contamination <input type="checkbox"/> Diagnostic Inaccuracy <input type="checkbox"/> Electrical		<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		<input type="checkbox"/> Product Mix Up <input type="checkbox"/> Software <input type="checkbox"/> Supply of Unlisted Device <input type="checkbox"/> Other		
Outcome of Incident (tick one only for each criteria)	Potential Outcome <input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> Temporary Injury <input type="checkbox"/> No Injury		Actual Outcome <input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> Temporary / Minor <input type="checkbox"/> No Injury		Injured Party <input checked="" type="checkbox"/> Patient <input type="checkbox"/> Operator <input type="checkbox"/> Not Applicable		
Reporter Type (Source Category)	Administrator <input type="checkbox"/> Medical <input type="checkbox"/> Lay		Clinician <input type="checkbox"/> General Practitioner <input type="checkbox"/> Specialist		Nurse <input type="checkbox"/> Community <input type="checkbox"/> Hospital <input type="checkbox"/> Private		
	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		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		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		
	Other <input type="checkbox"/> Blood Bank <input type="checkbox"/> Competitor <input type="checkbox"/> Hospital Supply Service <input type="checkbox"/> Patient / User <input checked="" type="checkbox"/> Sponsor <input type="checkbox"/> Other		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				
Risk Analysis (tick one only for each criteria)	Frequency <input type="checkbox"/> Frequently <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input checked="" type="checkbox"/> Unlikely		Severity <input type="checkbox"/> Life Threatening <input checked="" type="checkbox"/> Serious <input type="checkbox"/> Minor <input type="checkbox"/> Nil		Detectable <input checked="" type="checkbox"/> Likely <input type="checkbox"/> Occasionally <input type="checkbox"/> Rarely <input type="checkbox"/> Unlikely		