

Device Description:	HIP Prosthesis			DOCUMENT 23		
Date Assessed:	14.1.10		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	<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 .....	
(tick more than one if necessary)						
Outcome of Incident	Potential Outcome		Actual Outcome		Injured Party	
(tick one only for each criteria)	<input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> Temporary Injury <input type="checkbox"/> No Injury		<input type="checkbox"/> Death <input checked="" type="checkbox"/> Serious Injury <input type="checkbox"/> Temporary / Minor <input type="checkbox"/> No Injury		<input checked="" type="checkbox"/> Patient <input type="checkbox"/> Operator <input type="checkbox"/> Not Applicable	
Reporter Type	Administrator		Clinician		Nurse	
	<input type="checkbox"/> Medical <input type="checkbox"/> Lay		<input type="checkbox"/> General Practitioner <input type="checkbox"/> Specialist		<input type="checkbox"/> Community <input type="checkbox"/> Hospital <input type="checkbox"/> Private	
	Government Agency		Paramedical		Technical	
	<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		<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 .....		<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		Overseas Advice			
<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 .....		<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	Frequency		Severity		Detectable	
(tick one only for each criteria)	<input type="checkbox"/> Frequently <input type="checkbox"/> Sometimes <input type="checkbox"/> Rarely <input checked="" type="checkbox"/> Unlikely		<input type="checkbox"/> Life Threatening <input checked="" type="checkbox"/> Serious <input type="checkbox"/> Minor <input type="checkbox"/> Nil		<input checked="" type="checkbox"/> Likely <input type="checkbox"/> Occasionally <input type="checkbox"/> Rarely <input type="checkbox"/> Unlikely	