

Device Description:

HIP Prostheses

Date Assessed:

14.1.10

Assessed By:

Sample Requested:

 YES  
 NO

Sample Received:

 YES  
 NO

Received From:

 Reporter  
 Other

Device Type:

 Sterile  
 Reusable  
 Single Use

Classification:

 Urgent (48hrs) Expedite (5days) Routine (10days) Not Investigated

If Not Investigated:

Cause: .....

Result: .....

Recommendation: .....

Initial Recommendation:

 Investigate (to IRIS Meeting) Information Only Refer to Surveillance

Type of Incident

(tick more than one if necessary)

 Advertising Biocompatibility Contamination Diagnostic Inaccuracy Electrical Fails TGO / Standard Labelling/Product Info Material / Formulation Mechanical Packaging Product Mix Up Software Supply of Unlisted Device Other .....

Outcome of Incident

(tick one only for each criteria)

Potential Outcome

 Death  
 Serious Injury  
 Temporary Injury  
 No Injury

Actual Outcome

 Death  
 Serious Injury  
 Temporary / Minor  
 No Injury

Injured Party

 Patient  
 Operator  
 Not Applicable

Administrator

 Medical  
 Lay

Clinician

 General Practitioner  
 Specialist

Nurse

 Community  
 Hospital  
 Private

Government Agency

 Consumer Affairs  
 Coroner  
 TGA - Recalls  
 TGA - Labs  
 TGA - GMP  
 TGA - CAB  
 TGA - Surveillance

Paramedical

 Ambulance  
 Dentist  
 Pharmacist  
 Physiotherapist  
 Radiographer  
 Rehabilitation  
 Other .....

Technical

 Biomed Engineer  
 Biomed Technician  
 Clinical Technician  
 Hospital Engineer  
 Medical Physicist

Reporter Type

(Source Category)

Other

 Blood Bank  
 Competitor  
 Hospital Supply Service  
 Patient / User  
 Sponsor  
 Other .....

Overseas Advice

 ECRI  
 EU Vigilance  
 FDA (USA)  
 MDA (UK)  
 MDB (Canada)  
 Other .....

Risk Analysis

(tick one only for each criteria)

Frequency

 Frequently  
 Sometimes  
 Rarely  
 Unlikely

Severity

 Life Threatening  
 Serious  
 Minor  
 Nil

Detectable

 Likely  
 Occasionally  
 Rarely  
 Unlikely