Medical Device Adverse Event Report

1. Reporter Details

Name

Contact Information

Institution/Organization

2. Patient Information

Patient Age

Patient Gender

3. Device Information

Device Name

Model Number

Serial/Lot Number

Manufacturer

Date of Manufacture

Date of Implantation (if applicable)

4. Event Information

Event Date

Description of Event

Consequence/Outcome

5. Actions & Follow-up

Immediate Actions Taken

Device Disposition (Returned, Retained, etc.)

Other Relevant Information