

Reference No. _____

Preliminary Risk Analysis

Please complete AFTER the Problem Reporting Form is finished and all relevant information is collected

Date:

Reporter Information:

Name:

Address:

Contact Information:

H:

C:

E:

Is the report investigator a medical professional trained and experienced in using the device (eg. an expert)

Y N

If **YES**:

Profession:

Training:

If **NO**:

Professional:

Training:

Name and Occupation of professional supervising the Preliminary Risk:

Device Information:

Name of the device:

Device Identifier:

Lot number:

Quantity in stock:

Total quantity sold:

Length of time product has been on the market:

Has a death, injury, or disease been caused due to the use of the relevant medical device, either currently or historically?

Y N

If **YES**, explain:

Is the device a potential hazard to a vulnerable segment of the population (eg. children, surgical patients, the elderly, users with special needs, and/or users with disabilities?)

Y N

If **YES**, explain:

Based on the information provided in the related **Problem Reporting Form**, is there a high probability that the issue will occur again?

Y N

Explain rationale for answer:

What are the potential consequences for the problem with the medical device (eg. no potential consequences, minimal bodily harm, death, contribution to misdiagnosis)?

Was the user of the medical device (circle one):

Trained user or **Untrained user**

Experienced user or **Inexperienced user**

Specify job title or profession:

Based on the information collected in the **Problem Reporting Form**, was the problem an issue that most users would anticipate given proper training and experience?

Y N

Explain:

List any data provided to the reporter used to explain the reported problem (eg. scientific technical data, lab reports, medical records, chart notes):

Has an investigation already been conducted regarding this device?

Y N

If **YES**, explain:

Based on the information provided and Glia's risk estimation guidelines, what level of risk does the stated problem pose?

Type I

Type II

Type III

Explain rationale for risk analysis:

Based on the preliminary risk analysis, is a **Root Cause Investigation OR any other further action** necessary?

Y N

If **YES**:

Explain rationale:

Specific future action:

If **NO**:

Explain rationale:

Can the file be closed?

Other Comments:

File close date:

Signature: