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| **Persons Affected**  (Use participant ID or job title) | **Description of Device Deficiency** | **Actions Taken** | **Device Serial Number** | **Could Device Deficiency have led to SADE?**  (If yes, complete Safety Report Form) | **PI Assessment** | **PI Signature & date** | **CI Assessment** | **CI Signature & date** |
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**JRMO SOP 26d Associated Document 4**

**Device Deficiency Log**