|  |  |  |
| --- | --- | --- |
| **报告基本情况** |  | **Report Basic Situation** |
|  |  |  |
| 报告编码 |  | 1193118002025094119 |
| Report No. |  |  |
|  |  |  |
| 报告日期 |  | 2025-05-08 |
| Report Date |  |  |
|  |  |  |
| 报告人 |  | 周辉 |
| Reporter |  | ZhouHui |
|  |  |  |
| 单位名称 |  | 西门子医学诊断产品（上海）有限公司 |
| Customer name |  | SHD |
|  |  |  |
| 联系地址 |  | 中国（上海）自由贸易试验区英伦路38号四层410,411,412室 |
| Address |  | Room 410, 411 and 412, Floor 4, No. 38 Yinglun Road, Pilot Free Trade Zone, Shanghai, China |
|  |  |  |
| 联系人 |  | 周辉 |
| Contact Person |  | ZhouHui |
|  |  |  |
| 联系电话 |  | 13911135196 |
| Telphone No. |  |  |
|  |  |  |
| 发生地 |  | 境外 |
| Occurrence place |  | Out of China |
|  |  |  |
| **医疗器械情况** |  | **Medical Device Information** |
|  |  |  |
| 产品名称 |  | 维生素B12测定试剂盒(直接化学发光法) |
| Product Name |  | VB12 |
|  |  |  |
| 注册证编号 |  | 国械注进20162404435 |
| Registration no. |  |  |
|  |  |  |
| 型号 |  |  |
| Module |  |  |
|  |  |  |
| 规格 |  |  |
| Package |  |  |
|  |  |  |
| 产地 |  | 进口 |
| Origin of Country |  | Import |
|  |  |  |
| 管理类别 |  | Ⅱ类 |
| Class Type |  | Class II |
|  |  |  |
| 产品类别 |  | 体外诊断试剂 |
| Product type |  | IVD |
|  |  |  |
| 产品批号 |  | 83769299 |
| Product Lot |  |  |
|  |  |  |
| 产品编号 |  | 10995715 |
| Product No. |  |  |
|  |  |  |
| UDI |  | 00630414600284 |
|  |  |  |
| 生产日期 |  |  |
| Manufacturing Date |  |  |
|  |  |  |
| 有效期至 |  | 2025-12-07 |
| Expiration Date |  |  |
|  |  |  |
| **不良事件情况** |  | **Adverse Event Information** |
|  |  |  |
| 事件发生日期 |  | 2025-05-01 |
| Event Occurrence Date |  |  |
|  |  |  |
| 发现或获知日期 |  | 2025-05-07 |
| Knowledge Date |  |  |
|  |  |  |
| 伤害程度 |  | 其他 |
| Injury Type |  | Others |
|  |  |  |
| 伤害表现 |  |  |
| Injury |  |  |
|  |  |  |
| 器械故障表现 |  | 2025-00117461-1：高检测结果 |
| Device Malfunction Description |  | 2025-00117461-1：High Test Results |
|  |  |  |
| 姓名 |  |  |
| Patient Name |  |  |
|  |  |  |
| 出生日期 |  |  |
| Date of Birth |  |  |
|  |  |  |
| 年龄 |  | 73岁 |
| Age |  | 73-Years-Old |
|  |  |  |
| 性别 |  | 女 |
| Gender |  | Female |
|  |  |  |
| 病历号 |  |  |
| Medical Record No. |  |  |
|  |  |  |
| 既往病史 |  |  |
| Medical History |  |  |
|  |  |  |
| **使用情况** |  | **Usage Details** |
| 预期治疗疾病或作用 |  |  |
| Disease intended to treat or effect |  |  |
|  |  |  |
| 器械使用日期 |  | 2025-05-01 |
| Usage Date |  |  |
|  |  |  |
| 使用场所 |  | 医疗机构 |
| Usage site |  | Medical Institutions |
|  |  |  |
| 场所名称 |  | QUEST AT ROANOKE MEMORIAL HOSPITAL, UNITED STATES |
| Institution Name |  |  |
|  |  |  |
| 使用过程 |  | 客户报告称，在使用维生素B12（VB12）试剂批号299时，Atellica IM维生素B12（VB12）检测结果与重复检测结果不一致。 客户发现维生素B12（VB12）的质量控制（QC）失败，并对已报告初始结果的样本进行了重复检测。对于其中一个样本，初始结果高于重复检测结果，而重复检测结果被认为是正确的。 没有基于初始结果进行任何医疗干预。目前没有报告称观察到的问题导致患者受到伤害或其他不良后果。  Atellica IM维生素B12（VB12）结果（pg/mL）： 患者ID 年龄 性别 初始检测结果 重复检测结果 L388350786 73 女 688 135 |
| Usage Process |  | The customer reports observation of an Atellica IM Vitamin B12 (VB12) result which was discordant relative to repeat testing when using VB12 lot 299.  The customer identified a QC failure for VB12, and repeat-tested samples for which initial results had been reported. For one sample, the initial result was much higher than the repeat result, and the repeat result was considered correct.  There was no medical intervention performed on the basis of the initial result. There are no reports of patient harm or any other adverse consequences in association with the observed issue.  Atellica IM VB12 results (pg/mL):  Patient ID Age Sex Initial Repeat  L388350786 73 F 688 135 |
|  |  |  |
| 合并用药/械情况说明 |  |  |
| Drug/device Combination Description |  |  |
|  |  |  |
| **事件调查** |  | **Event Investigation** |
|  |  |  |
| 是否开展了调查 |  | 是 |
| If carry out investigation |  | Yes |
|  |  |  |
| 调查情况 |  | 客户报告称，Atellica IM维生素B12（VB12）检测结果与重复检测结果不一致。 该检测项目的使用说明书（IFU）在“检验结果的解释”部分指出： “检测结果的判读务必结合病人病史、临床表现和其他发现情况进行。” 西门子正在对该事件进行调查。  2025-05-16 更新信息:  客户报告观察到一个与重复检测结果不一致的Atellica IM维生素B12（VB12）检测结果。  西门子已结束调查。  对客户维生素B12的质量控制（QC）结果进行审查发现，所有三个水平的QC结果回收均超出范围。在产生失败的QC结果时，未停止VB12患者的检测。  客户通过重新校准检测方法解决了其超出范围的QC问题，随后的检测未出现问题。  由于不一致的结果无法复现，因此没有必要将受影响的样本退回进行进一步调查。  尽管未能确定不一致结果的具体原因，但未发现系统性产品问题。客户已恢复正常运营，通过重新校准检测方法解决了观察到的问题。 |
| Investigation description |  | A customer reported observation of Atellica IM Vitamin B12 (VB12) results which were discordant relative to repeat testing.  The assay's Instructions for Use (IFU) states the following, under Interpretation of Results:  "Results of this assay should always be interpreted in conjunction with the patient’s medical history, clinical presentation, and other findings."  Siemens is investigating.  2025-05-16 update information:  A customer reported observation of an Atellica IM Vitamin B12 (VB12) result which was discordant relative to repeat testing.  Siemens has concluded investigation.  Review of customer Quality Control (QC) results for VB12 showed that QC was out of range for all three levels. VB12 patient testing was not halted when the failing QC results were produced.  The customer resolved their out-of-range QC issue by recalibrating the assay, and subsequent testing was without issue.  Return of the affected sample for further investigation is not warranted as the discordant result was not reproducible.  Although a specific cause for the discordant result could not be identified, no systemic product problem was found.  The customer is operational, and the observed issue was resolved by recalibrating the assay. |
|  |  |  |
| **评价结果** |  | **Evaluation Result** |
|  |  |  |
| 关联性评价 |  | 无法确定 |
| Relative Evaluation |  | Undetermined |
|  |  |  |
| 事件原因分析 |  | 尽管未能确定不一致结果的具体原因，但未发现系统性产品问题。 不良事件来源：投诉。  Although a specific cause for the discordant result could not be identified, no systemic product problem was found. |
| Event Reason Analysis |  | Adverse events source: Complaints. |
|  |  |  |
| 是否需要开展产品风险评价 |  | 否 |
| If need initiate Product Risk Assessment |  | No |
|  |  |  |
| 计划提交时间 |  |  |
| Plan submission Date |  |  |
|  |  |  |
| **控制措施** |  | **Control Measure** |
|  |  |  |
| 是否已采取控制措施 |  | 否 |
| If has taken control measure |  | No |
|  |  |  |
| 具体控制措施 |  |  |
| Control measure details |  |  |
|  |  |  |
| 未采取控制措施原因 |  | 客户已恢复正常运营，通过重新校准检测方法解决了观察到的问题。 |
| No control measure reason |  | The customer is operational, and the observed issue was resolved by recalibrating the assay. |