**DA Determined Cause Classifications‡**

| Determined Cause | Classification | FDA Determined Cause |
|---|---|---|
| | *Other/Under Investigation* | |
| ponent change control | | Other |
| ponent design/selection | | Pending |
| | | Under Investigation by firm |
| *ol** | | Unknown/Undetermined by |
| ce Design | | |
| ned device change control | *Packaging* | |
| | | Package design/selection |
| | | Packaging |
| oyee error | | Packaging change control |
| rror | | Packaging process control |
| | *Process* | |
| oment maintenance | | Process change control |
| | | Process control† |
| | | Process design |
| in labeling | | |
| ling Change Control | *Software* | |
| ling design | | Software change control |
| ling False and Misleading | | Software design |
| ling mix-ups | | Software design (manufactu |
| rect or no expiration date | | Software Design Change |
| | | Software in the Use Environ |
| | | Software Manufacturing/So |
| | | Deployment |
| conforming Material/Component | | |
| ufacturing material removal | *Radiation Control for Health and Safety Act* | |
| rial/Component Contamination | | Radiation Control for Health |
| d-up of materials/components | | |
| se of Material/Component prior to receiving test results | | |

al processes used within quality management systems (QMS) to ensure that changes to a product or system are introduc

eloping, conducting, controlling, and monitoring production processes to ensure that a device conforms to its specificatic

letermined causes were omitted, as 0% of ROD recalls and <0.4% of other device recalls cited them: Counterfeit, Enviro
s, Storage, Vendor change control