Statement of the problem

5.

Evidence of performing a design review on the Tom Thumb design change in 2005 could not be provided at this assessment.

5.

Root Cause Analysis

We did not have evidence of performing a design review on the Tom Thumb design change in 2005.

What should have been present and wasn't, was a statement saying that performing a design review was not required in this case on the Tom Thumb file. For the relevant reasoning please see below:

The customer requested a design modification in 2005. Which was a request for units made to the original design specification, prior to its change to 15mm 1994.

Meaning it was already a proven design. So a formal design validation was not required.

We do have a design change document that states that the device would be required to pass our QA safety tests. We are confident that the tests were done and have a serial number for the sample device with the modified design, but the QA report has not been added to the technical file.

We did contact MHRA regarding this request at the time.

We did not however enter a statement to that effect in to the technical file.

5.

Immediate Action

It is not possible to add the statement retrospectively saying that a formal design review was not required, in this case, on the Tom Thumb file.

We will attempt to locate the original QA report for the sample device within the paper archives, along with any other archived evaluation reports.

5.

Corrective Action

This is a historic issue and as such we no longer carry out the tasks, relating to this, in the same way.

We will update the QMS procedures to ensure we do not miss information again and collate them in a way that makes them easy to find, monitor and review.

In this case the Post market Surveillance was up dated in 2012 and would have prevented this from being missed.

We can ensure relevant historic documents are brought in to the new system when required, but in this case it would not have helped.