30-Day Notice Table of Contents

Cover Letter

- Include a generic description of the change using the terms that you wouldn't mind appearing on FDA's supplement approval webpage
- Make sure your email address is easily identifiable because emails will likely be sent instead of faxes.

Section 1 Submission Purpose

- Executive Summary (similar to that used in a Real Time Review)
- Explanation of the proposed change(s) in a manner that can be understood by a reviewer that has limited knowledge of the product and process technology.
- Summary of applicable previous FDA approvals/submissions/correspondence/PMA section references applicable to proposed change(s)
- List of affected PMA numbers (Bundled PMAs)
- List of the manufacturing facilities/sites affected by the proposed change including the FDA Establishment Registration numbers.
- Consider using pictures of products affected and descriptions of products so the FDA reviewer will have an understanding and the context of the proposed changes they will review in the submission

Section 2 Description of Change

- Summarize the "Current process" vs. the "Proposed process" to clearly identify what is changing
    - If something is isnt changing state so (e.g., specifications, materials, inspections, etc).
- Use tables, diagrams, and flow charts to clearly describe the current process vs. the proposed process/change(s)
- Use pictures/diagrams/video to illustrate the affected processes and or equipment or product
- Use "screen snaps" to clearly depict software/electronic recording system changes

Section 3 Reason for Change

- Provide the "motivation" for the change; cost reduction, yield improvement, operator safety, new equipment, software update, electronic records, etc.
- Indicate if the change is the result of failures, complaints, Field Action or Adverse Events.

Section 4 Assessment of Risk

Provide a description of the risks specific to this change. This section should not become a summary of procedures for risk assessment.

- Refer to the AdvaMed "Risk Assessment Considerations" document
- Describe the company's Risk Assessment method used (e.g., FMEA, Fault Tree Analysis, ALARP)
- Explain what tests were performed and why, likewise explain what tests not performed and why

- Refer to and recognize applicable parts of ISO14971 as represented by your companies SOP(s)

Section 5 Summary of the Information Supporting the Change

Section 5.1 Summary of Procedures to Evaluate and Document Changes to the Manufacturing Process

- provide brief summary of procedures and state if it is the same procedure as described in a previous submission

Section 5.2 Statistical Rationale for Routine Sampling and Measurement

- If this section is not applicable, don't delete it, state why its not applicable

Section 5.3 Monitor and Control of Process Parameters for Changed Procedures requiring Validation

- If this section is not applicable state why its not applicable

Section 5.4 Summary of Validation Studies

- Describe the testing performed using summary text and use of tables and charts to present complex information and data sets.
- provide statistical rationales for the sample sizes used in testing and clearly justify why the device models tested are representative of the entire product range or are otherwise worst case.
- Test reports and supporting documentation in the submission can be presented according to the companies Quality System Requirements. For example; IQ/OQ/PQ and other Process Verification and Validation approaches.
- Add supporting test reports and documents as Appendices (Section 7) to the submission. Include hyperlinks in the electronic copies submitted to FDA.
- Describe the "statistical methods" applicable to the testing and the rationale for use
- Provide justification and rationale for the "acceptance criteria" used
- Summary of Deviation(s) and the resolutions and explanation of the impact of the deviation on the results
- Clearly state what the results mean (e.g,, The cpk is X; therefore…)
- NOTE: If there are any changes to acceptance activities (e.g., receiving, in-process, finished) be sure to fully describe the change and summarize the statistical rationales for sampling techniques.
- NOTE: If there are any changes to a cleanroom or manufacturing environment, provide a summary of that change and describe the testing and environmental controls to support that the change does not have an adverse effect on the environment.

Section 5.5 Summary of Change Controls

- Summary of Change Review and Control Process used by the company to manage the change

Section 5.6 Summary of Purchasing Controls Procedures (Manufacturing Changes Involving Changes in Components, Raw Materials, or Suppliers or Manufacturing Changes Involving Use of New Contractor for Manufacturing or Quality Control Testing)

- If this section is not applicable to your change, don't delete this section, just state that there were no changes involving suppliers or contractors.
- Describe the type and extent of control to be exercised over the component or raw material, including specifications for the incoming material and a description of in-coming acceptance activities (This should be specific to this change and not a general summary of Quality System SOPs)

Section 6 Conclusion

- Summary statement regarding the safety and effectiveness of the proposed change

Section 7 Statement of Conformity

- Statement of Conformity (from the FDA guidance document) which should reference both 520(f) of the FDCA and 21 CFR 820

Appendices

- Include Appendices applicable to the submission.