

Documenting Changes Using the 510(k) Guidance

In October 2017, FDA published two final guidance documents to help manufacturers determine when a device change requires a new 510(k). The guidance documents are:

Deciding When to Submit a 510(k) for a Change to an Existing Device

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

While there are two guidance documents, they work together to help the manufacturer determine whether the change or changes meet the regulatory threshold in §807.81(a)(3). It has two parts: (i) is a significant effect on safety or effectiveness of the device and (ii) is a major change in the intended use. Either part triggers a new 510(k). One issue, address by the guidance documents, whether a change has a **significant** effect.

There are two ways to change a device. One is a design change under §820.30(i) and the other is a production/process change under §820.70(b). (QSIT says that these two sub-sections are redundant.) For either type of change, evaluate it to determine if it “triggers the regulatory threshold for submission”. Assume not. Document the evaluation, make the change, and market the device.

However, there could be a number of non-significant changes that, when applied cumulatively, trigger the threshold. They bring the device outside the current cleared 510(k). The guidance documents call this the “original device”. While no individual change triggered the threshold, the cumulative set of change do.

The idea in the guidance documents is to evaluate each individual change and the cumulative changes since the “original device”. (This idea is also in the 1997 guidance, so it is not new.) If either change type (individual or cumulative) triggers the threshold, then submit a new 510(k) and describe all changes (including the ones that didn’t trigger the threshold) since the “original device”.

The flowcharts are useful in evaluating the individual change, but are not so good on the cumulative changes. Use the information in the most recently cleared 510(k) to define the “boundaries” of the device. If an individual change that doesn’t trigger the threshold, then evaluate the device after the change to ensure it is still within the boundaries. The concern is that each incremental change may not trigger the threshold, but, as they accumulate, the device to be marketed is too far from the “original device”.