

The “Catch-Up” 510(k) — A Submission Often Overlooked

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This article discusses “catch-up” 510(k) submissions, circumstances under which a “catch-up” 510(k) submission should be considered, content and timing of such a submission and procedural recommendations for this submission type.

Background

The majority of medical devices are brought to market in the United States through the 510(k) pathway. A 510(k) clearance is based on FDA’s review and concurrence with the submitter’s substantial equivalence determination, allowing market introduction of a new or modified device.

Upon clearance of a 510(k) and throughout the product lifecycle until obsolescence, 510(k) holders are responsible for evaluating changes to their product to determine whether a new 510(k) is required prior to market introduction for a modified product. This regulatory requirement is codified in 21 CFR 807.81 (a).(1)

FDA’s current thinking on this topic is documented in the 10 January 1997 guidance “Deciding When to Submit a 510(k) for a Change to an Existing Device.”(2) As stated in the regulation and corresponding guidance document, the regulatory threshold for submitting a new 510(k) is based on a change in intended use or other change that could significantly affect the safety and effectiveness of the device. Changes deemed non-significant are not required to be reported to and reviewed by FDA as part of a 510(k) submission, but must be thoroughly documented and justified in a 510(k) holder’s internal files (often known in the medical device industry as a “letter to file” or “memo to file”) which may be reviewed during FDA inspections.

Many types of changes may be implemented over the product lifecycle by 510(k) holders, including changes to materials, performance specifications and labeling, among others. Although many of these individual changes may not be deemed significant and can

be documented internally, when changes implemented over time are assessed in sum, the current device may differ significantly from the 510(k)-cleared device. In this case, submission of a new 510(k) is warranted demonstrating the marketed device is *at least* as safe and effective as the cleared device.

“Catch-Up” 510(k) Definition

A 510(k) to bring FDA up-to-date on non-significant changes implemented since the last 510(k) clearance is often known within the medical device industry as a “catch-up” 510(k). A “catch-up” 510(k) is not explicitly described in regulation or guidance documents and is often overlooked by 510(k) holders for this reason.

Throughout a product’s lifecycle, 510(k) holders anticipate two regulatory pathways in implementing changes: 1. submitting a new 510(k) (either Special or Traditional 510(k)) for significant changes or changes which affect the intended use of the device or 2. preparing internal documentation, e.g., “letter to file” for non-significant changes. The reason behind this is that the 510(k) changes guidance addresses individual changes implemented at a single point in time, but does not address incremental, non-significant changes that could, in sum, be significant when evaluating the device holistically.

This article will address “catch-up” 510(k) submissions, including circumstances under which a “catch-up” 510(k) submission should be considered, content and timing of such a submission, and recommendations for standard operating procedures for this submission type.

Evaluating the Need for a “Catch-Up” 510(k)

Although 510(k) holders have change management and associated regulatory assessment procedures requiring review and evaluation of individual changes to a device or multiple changes being implemented at a single point in time, these procedures often do not take into account the sum total of changes implemented since the last 510(k) clearance. Accordingly, 510(k) holders should periodically review summative changes to a cleared device to determine whether the current device differs significantly from the cleared device.

Consider a scenario where a company received clearance for a general surgery ablation system in 2010. Over the ensuing five years, modifications were implemented inclusive of minor modifications to the device software; improvements to the user manual (addition of new images, clarification of steps of use); operating temperature specifications; minor changes to electrical components (specifications unchanged); modifications to the ablation probe design (fractional increase in tip size, design of handle); minor changes in the allowable range of the energy source generator; and materials change to the buttons of the device interface.

Each of these changes were implemented separately over time through engineering change notifications and associated “letters to file,” and was deemed “non-significant.” However, when looking at the model of device comprising these changes, the company’s regulatory affairs director believes the new device should be holistically validated through new usability testing accounting for differences in the probe design ergonomics and in the software/labeling changes which give the user a very different experience than the cleared prior model. Thus, a 510(k) should likely be filed.

It would be ‘best practice’ to develop a procedure or incorporate into a related procedure, steps to ensure these reviews take place and to address the content of the “catch-up” 510(k).

Other Considerations for Submitting a “Catch-Up” 510(k)

In addition to bringing FDA up-to-date on incremental non-significant changes because a 510(k) holder has determined the current device may significantly differ from the cleared device, 510(k) holders also may consider submitting a “catch-up” 510(k) for other reasons.

For example, a 510(k) holder may be interested in making a significant modification to its 510(k)-cleared device in the future, such as a “next generation” product or an expansion of indications for use. In a 510(k) submitted for a significant change, it also is necessary to update FDA on any *non-significant* changes implemented since the last 510(k)

clearance (documented in engineering change notifications and “letters to file”) in addition to describing the currently proposed modification(s). Bundling these updates with the pertinent information for a product improvement or indications change could result in a complex submission, potentially delaying 510(k) clearance and introduction of a product to market. Thus, it would be beneficial for a medical device company to submit a “catch-up” 510(k) before the need arises for a 510(k) to obtain clearance for a significant modification.

Another potential consideration for submitting a “catch-up” 510(k) is in mitigating compliance risk. During a retrospective review of “letters to file” for a cleared device, a 510(k) holder may determine one or more “letters to file” were erroneous or overreaching in determining the significance of a change(s). In this case, a 510(k) should have been submitted prior to implementing the change(s). In such circumstances, a 510(k) holder may choose to submit a “catch-up” 510(k) in an effort to mitigate the risk of a Form 483 or “Warning Letter” resulting from an FDA inspection.

A 510(k) holder also may wish to consider submitting a “catch-up” 510(k) to facilitate international product registrations. In many cases, a product must have an existing 510(k) clearance to be registered internationally (or having clearance significantly decreases the regulatory burden for registration of the product). In addition to a *Certificate to Foreign Government* (CFG) and/or 510(k) clearance letter, in-country representation or a Competent Authority will often request a certification letter from a 510(k) holder, indicating the device for which registration is sought is equivalent to the device cleared in the 510(k) referenced or provided. This type of request may originate from a simple device tradename change. However, if a number of years have passed since 510(k) clearance and/or the in-country representation or Competent Authority is aware the 510(k) holder implemented numerous changes since clearance, this certification letter may not be sufficient and an updated clearance may be warranted.

Format and Content of a “Catch-Up” 510(k)

If a “catch-up” 510(k) is required, a 510(k) holder must decide which format is appropriate, as there is no prescribed format for a “catch-up” 510(k). The criteria for a Special 510(k) require the device to have the same indications for use and fundamental scientific technology as the predicate, and changes deemed non-significant should meet these criteria, making the Special 510(k) an appropriate type of submission for a “catch-up” 510(k) if desired. However, depending upon the number of changes and ease with which they can be presented along with the extent of verification and validation activities performed in support of these changes, a Traditional 510(k) submission may be preferable.

A “catch-up” 510(k) should meet the content and format requirements of the submission type chosen, as described in the regulation and guidance documents. The submission cover letter and executive summary should indicate the purpose of the submission; bringing FDA up-to-date on changes implemented through internal documentation since the last 510(k) clearance. This also should include an itemized description of and reason for the changes as well as the information being included in the submission pertaining to those changes, such as risk information or verification and validation testing. The predicate device described throughout the submission is the device last cleared and the “new device” (subject of the submission) is the current device being marketed, encompassing all changes implemented since the last clearance. If a Special 510(k) is being submitted, risk information, a description of verification and validation activities, and respective acceptance criteria should be provided specific to each change. If a Traditional 510(k) is being submitted, comprehensive testing documentation in support of the changes should be provided.

Timing and FDA Action on “Catch-Up” 510(k)s

The timing for a “catch-up” 510(k) should be determined based on the reason for submitting the “catch-up” 510(k) and company business needs. If the 510(k) is being submitted for compliance risk mitigation, the “catch-up” 510(k) should be submitted as soon as possible, especially if an FDA inspection is imminent. If the submission will be used to obtain an updated clearance letter to facilitate international registrations, the timing of the “catch-up” 510(k) should take into account the timing for international registration

documentation compilation, review and approval by the Competent Authority as well as the desired timing for market launch.

Provided the changes are clearly described and justified, those submitting a “catch-up” 510(k)s should anticipate a more streamlined and timely review by FDA in contrast to a submission for a next generation device or expanded indication, for example. FDA will work collaboratively with those who submit a “catch-up” 510(k) to resolve any questions or issues. And, as long as FDA does not identify any safety concerns, companies should be able to continue marketing their devices while a “catch-up” 510(k) is under FDA review.

Conclusion

Deciding when to submit a 510(k) for a change to an existing medical device is never easy. In addition to the careful considerations necessary for evaluating individual changes or changes implemented at a single point in time, a 510(k) holder also should have a documented process in place for evaluating a medical device holistically, inclusive of changes implemented throughout the product lifecycle. Whether a 510(k) is submitted for a change or changes to a cleared device also may be influenced by a company’s tolerance for compliance risk and their longer-term regulatory strategy for device lifecycle management. Further, FDA intends to issue draft guidance, updating the 1997 final guidance, on assessing changes to a 510(k)-cleared device during FY 2016.⁽³⁾ While it is not likely holistic evaluation of changes and “catch-up” 510(k)s will be directly addressed, this new draft guidance document may provide further clarity on the 510(k) decision making process and potentially offer more examples to help guide a manufacturer’s decision to submit a 510(k).

References

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