FDA Fact Sheets:
Premarket Notification – 510(k)

A premarket notification, or 510(k) submission, is the mechanism through which the majority of medical devices obtain U.S. marketing clearance. A 510(k) submission is required for any device intended for human use unless the device is exempt by regulation (most Class I and select Class II devices) or is a Class III device.

A 510(k) submission must demonstrate that the device is substantially equivalent (SE) to one or more devices legally marketed in the U.S with the same intended use. If the device is found SE by FDA, it is cleared for commercial distribution and may be marketed. If the device is found not substantially equivalent (NSE), it will require submission to FDA of a premarket approval application (PMA) to obtain marketing approval or be cleared via the *de novo* process.

A determination of SE indicates that the device is at least as safe and effective as a similar, legally marketed device (the "predicate"). A device may be found to be SE if it has the same intended use and technological characteristics as the predicate, or if it has the same intended use but different technological characteristics, as long as the device is at least as safe and effective as the predicate and raises no new questions of safety and effectiveness.

A new 510(k) submission is required for a device already in commercial distribution if: 1) there are changes or modifications to the device that could significantly affect its safety or effectiveness, or 2) there is a proposed change or modification to the intended use of the device.

Required information in a 510(k) submission includes: device classification; device description; comparison with predicate device(s); intended use; proposed labeling; and applicable information on performance testing, sterilization, biocompatibility, expiration, etc. Under the current Medical Device User Fee Act agreement, FDA commits to reaching a decision on 95 percent of 510(k)s in 90 FDA days.