



Emergo Group assists medical device companies worldwide with US FDA classification, registration, representation and quality system compliance as shown below.

Predicate device research

The US FDA 510(k) Premarket Notification submission requires you to demonstrate that your device is safe and effective by proving substantial equivalence to a legally marketed device (predicate device). Because FDA device classification is not rules based (as in Europe), finding a suitable predicate using the FDA database can be challenging. We can assist you in this process. However, if classification cannot be determined or a predicate does not exist, we can help obtain a formal classification opinion from the FDA. Alternatively, we can guide you through the "de novo" process if your product is truly innovative and is not considered a Class III or high-risk device..

FDA 510(k) submission preparation

Most Class II devices must obtain 510(k) clearance from the FDA, and as noted, you must demonstrate that your device is substantially equivalent to a device that has already been cleared by the FDA. As hundreds of guidance documents exist for specific devices and technologies, 510(k) submissions can be very complicated and time consuming to prepare. If you are introducing a device to the US market, let us navigate the FDA process for you. We have successfully obtained 510(k) clearance for hundreds of devices and can advise you on testing requirements, clinical data, validation and other issues the FDA requires you to address as part of the submission.

Quality System Regulation (QSR) compliance

The US FDA quality system requirements (21 CFR Part 820) were created many years before ISO 13485. As a result, they differ and the US FDA does not recognize ISO 13485 certification. Emergo Group implements integrated quality management systems that meet the US FDA QSR (also known as cGMP – current Good Manufacturing Practice) and also comply with the requirements of Europe and Canada. If desired, we can also make your system compliant with the requirements of Brazil and Japan.

QSR quality system audits

Unlike ISO 13485, there is no QSR certification program and no quality system compliance certificate is issued by the FDA. Instead, the FDA conducts random inspections to determine compliance with 21 CFR Part 820. These inspections are rigorous and the FDA often issues Form 483 and Warning Letters to companies found to be non compliant. For this reason, we support many companies in periodic internal audits of their quality system as well as their critical suppliers worldwide. This can be done prior to device clearance and thereafter as well.

FDA US Agent representation

In-country representation is required for all companies commercializing in the US. If you do not have a US location, you can appoint Emergo Group to act as your independent, professional regulatory representative to the FDA, called a US Agent. We represent hundreds of medical device manufacturers worldwide in this role.

* Approximately 5% of Class I devices require a 510(k) submission.

** FDA approval of Class III devices is a lengthy and complicated process. This is an extremely simplified version of the steps required for Class III. Premarket Approval (PMA). Consult the FDA website at www.fda.gov/medicaldevices for more information.

¹ 21 CFR Part 820 (Quality System Regulation) is the section of the US Code of Federal Regulations that specifies Quality Management System requirements for device manufacturers. The Quality System Regulation is also commonly known as Good Manufacturing Practice (GMP). A few Class I device manufacturers are not required to comply with all GMPs.

^{^^} Clinical trials are required for Class III devices (and some Class II devices). Prior to initiating a Class III clinical trial, an Investigational Device Exemption (IDE) must be approved by FDA. A few Class II devices require the submission of clinical data with the 510(k) submission. Prior to initiating the clinical trial for a Class II device, an IDE and/or the Clinical Protocol must be approved by an Institutional Review Board (IRB).

^{^^^} The FDA will conduct an inspection of ALL major suppliers involved in the design, development and manufacturing of a Class III device and these facilities must have a QSR compliant quality system in place before the PMA application is approved by the FDA.