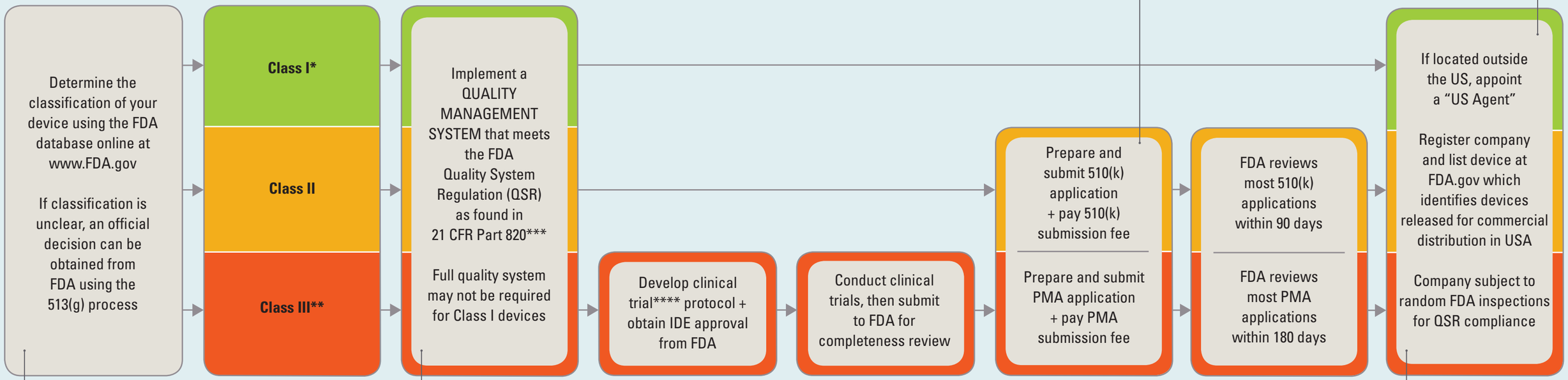
An overview of the USA regulatory process for medical devices and how we can help.

Emergo Group has been helping medical device and IVD companies with international regulatory and quality assurance issues since 1997. Whether you are entering the US market for the first time or introducing another new device, we can assist with everything from US FDA Quality System Regulation*** (QSR) compliance and audits, to 510(k) preparation and distributor qualification. With offices in North America, Europe, Asia and Australia, Emergo can help you obtain regulatory clearance, maintain compliance and increase your sales in the world's largest medical device markets.

FDA 510(k) preparation with fast turnaround
If you are introducing a new device to the US market, let us navigate the FDA process for you. We have prepared hundreds of 510(k) submissions and have experience with a wide range of devices. We can advise you on testing requirements, validation and other issues the FDA requires you to address as part of the 510(k) submission.

US Agent representation for companies worldwide
If you have no US location, you can appoint Emergo Group to act as your professional regulatory representative to the FDA, called a "US Agent." We represent companies from over 35 countries worldwide in this role.



Emergo can help determine FDA classification
Devices can usually be easily classified using the FDA databases online. However, if classification cannot be determined or no "predicate" device matches your device, we can research it for you or prepare a detailed 513(g) submission asking for an official device classification and determination from the FDA.

An Emergo QMS meets most global requirements
Most manufacturers are required to have a Quality Management System that meets the FDA Quality System Regulation (QSR). We have implemented QSR-compliant quality systems for hundreds of device companies and, if desired, we can implement ISO 13485 at the same time.

Let us assess the compliance of your Quality Management System
Unlike ISO 13485, there is no Quality System Regulation (QSR) certification program and no certificate is issued by the FDA. Instead, FDA conducts random post-marketing inspections to determine compliance. To ascertain their level of QSR compliance, many companies ask us to perform internal audits of their quality system and critical suppliers. This can be done prior to device clearance and thereafter as well.

* A small number 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 Pre Market Approval (PMA). Consult the FDA website for more information.
*** 21 CFR Part 820 (Quality System Regulation) is the section of the US Code of Federal Regulations that specifies current Quality Management System requirements for device manufacturers. The Quality System Regulation is also commonly known as Good Manufacturing Practice (GMP).
**** Clinical trials are required for Class III devices (and some Class II devices). Prior to initiating the 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 must be approved by an Institutional Review Board (IRB).

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