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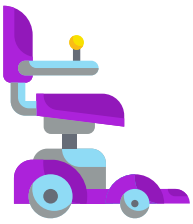
# pathways to market for medical devices in the U.S.

Medical devices are regulated by the Center for Devices and Radiological Health (CDRH) at the FDA. There are several premarket submission pathways for medical devices.



## Exempt from Premarket Submission

This applies to most low risk Class I devices.

## Premarket Notification (510(k))

The most commonly used pathway, a 510(k) submission is required for some Class I and most Class II devices. The Sponsor must show that their device is substantially equivalent to an existing device that is already cleared and marketed.

## Premarket Notification (510(k))

A PMA is the most stringent device marketing application and typically requires clinical data. It is required for high risk, Class III devices



Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.
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Risk Level

## De Novo

If you're bringing a device to market for which there is no legally marketed predicate device, but that device is low or moderate risk, the de novo pathway gives you the opportunity to avoid the more rigorous PMA route.

## Humanitarian Device Exemption (HDE)

This program seeks to encourage device companies to bring treatments onto the market for very small populations. The regulatory requirement is that humanitarian use devices treat or diagnose conditions that affect fewer than 8,OOO people in the U.S. per year.

## Product Development Protocol (PDP)

The PDP is essentially a contract that allows the sponsor to reach early agreement with the FDA concerning how to demonstrate the safety and effectiveness of a new device. The manufacturer can proceed with device development and testing, then once the PDP has been declared completed by FDA, it's considered to have an approved PMA.

## Custom Device Exemption (CDE)

The least used pathway, CDE has historically been used for dental applications, prescription glasses, and prosthetic limbs. No more than 5 units per year of such a device can be marketed.

## Expanded Access Option (Compassionate and Emergency Use)

The expanded access pathway allows an investigational device to be used, outside of a clinical trial, in situations where a seriously ill patient has few, if any, alternatives.

## what is your regulatory strategy?

Let ProPharma help you determine which of the regulatory pathways will enable you to get your product successfully on the market in a timely and cost-effective manner