

De Novo Classification - Novel Devices

De Novo is an **alternative pathway** for **new low-to-moderate risk devices without a predicate**

NEW

Novel Device

Innovative devices that cannot be compared to existing devices



Low-Moderate Risk

Risk level that can be classified as Class I or II



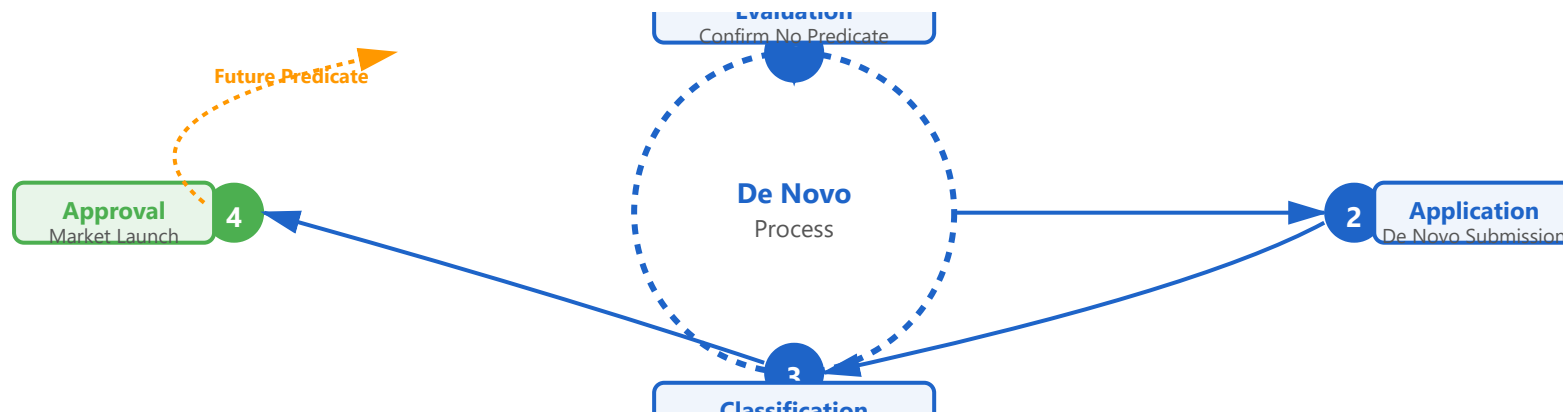
Special Controls

Special management measures for risk mitigation



Future Predicate

Can be used as a predicate for future 510(k)s



Key Point: After De Novo approval, the device can be used as a predicate for similar future devices, facilitating market entry for innovative technologies