Tabella 2 – Percorsi regolatori dei Dispositivi Medici in USA

Regulatory pathway	510k	De novo	Premarket approval
Product risk levels	Class I and II	Class I and II	Class III
FDA decision type	Cleared	Granted	Approved
Requires a predicate	Yes	No	No
Decision criteria	Product demonstrates "substantial equivalence" to a predicate (e.g., no independent assessment of the product required)	Probable benefits of the product outweigh probable risks	Requires independent assessment of the product's safety and effectiveness