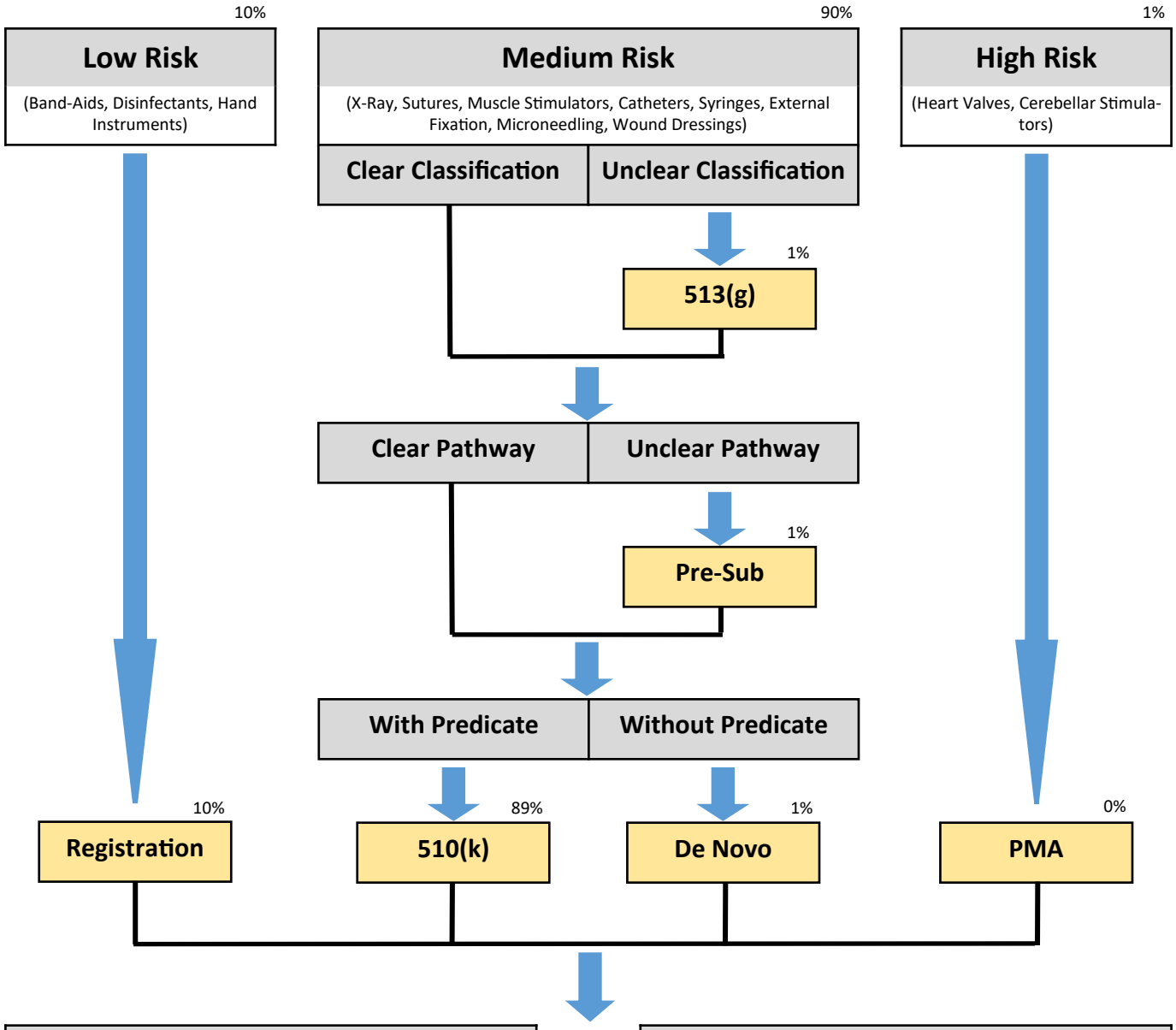
Medical Device Pathways Through US FDA



Testing Requirements

Electrical Safety, EMC, Usability—powered devices
Biocompatibility—components that touch patient or consumer
Sterility (Validation, Package Integrity, Shelf Life)—sterile devices
Pyrogenicity—implants & devices that can cause febrile reactions
Software Verification &Validation, Hazard Analysis—devices with SW
Performance (Bench Tests)—all devices
Performance (Animal, Clinical)—most PMA & some 510k/De Novo
Cybersecurity—devices vulnerable to security breaches
Home Healthcare—most products used in home

Other Requirements

Registration—manufacturers, initial importers, repackage/relabelers (online payment of annual establishment registration fee)
Device Listing—all registrants
Labeling—all devices
Universal Device Identification (UDI)—all devices (marked on device & label, with registration in global database through authorized issuing agency)
GMP—meet Quality System Regulation for most devices (with periodic FDA audits); includes design controls, record keeping, complaint files, & device master record (21 CFR 820)

% = Breakdown of medical device engagements over past 5 years

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