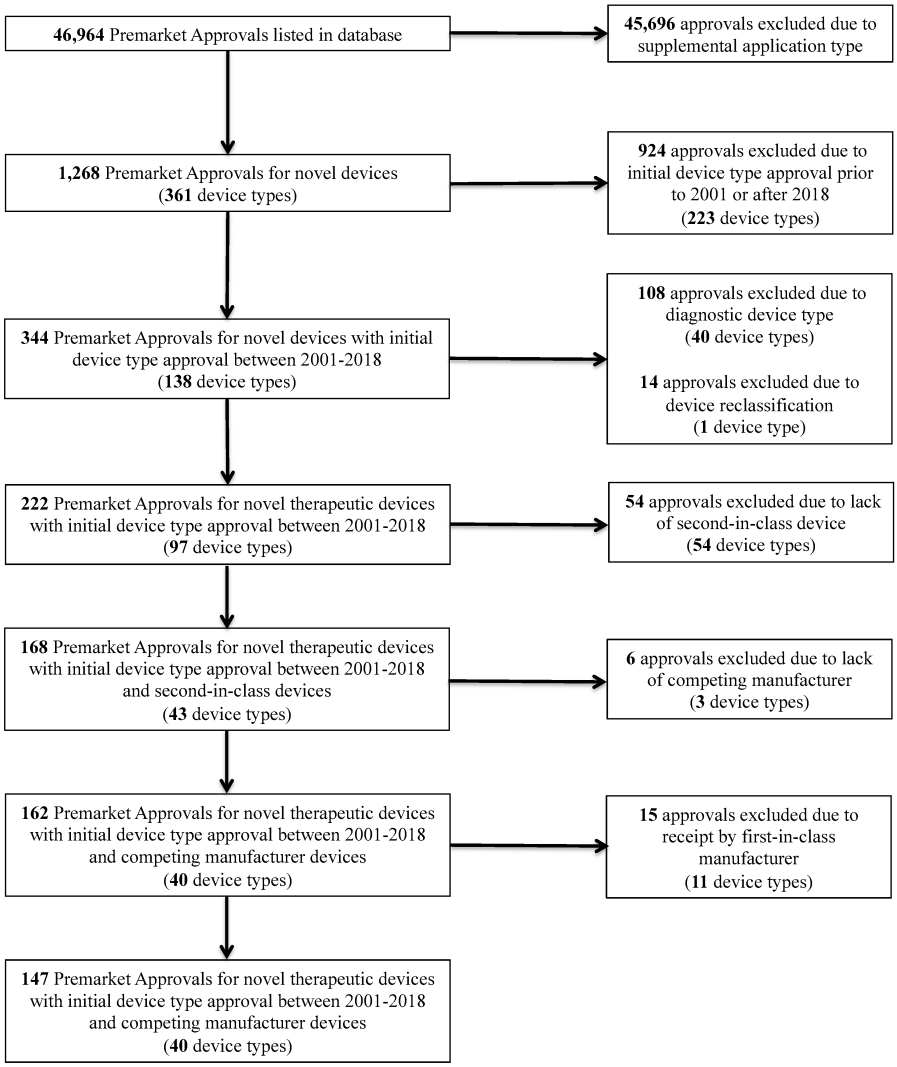
Supplemental Figure



Cohort of Novel High-Risk Therapeutic Device Types Receiving Initial FDA Premarket Approval with Subsequent Intra-Class Competition, 2001-2018

Caption: FDA denotes U.S. Food and Drug Administration. Non-wearable external defibrillators (1 device type, 14 approvals) were excluded because the FDA began requiring Premarket Approval for these commercial available (i.e., non-novel devices) devices in 2015 as a result of risk reclassification under the 515 Initiative.