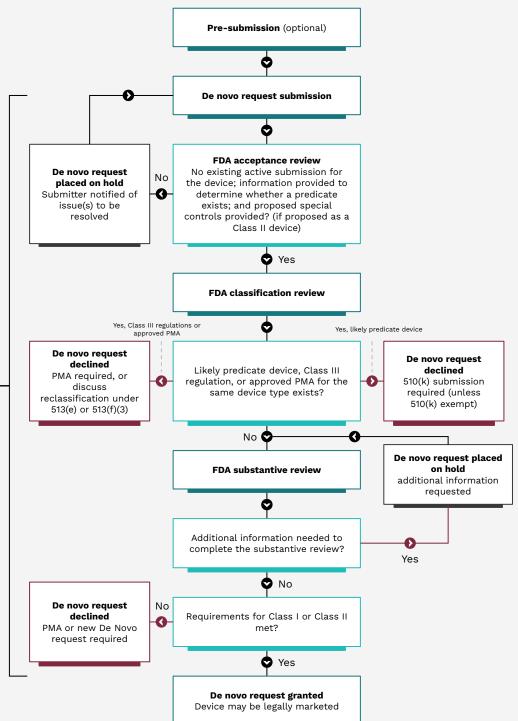
De Novo Request Review Process







</= 120 FDA days to Grant/Decline