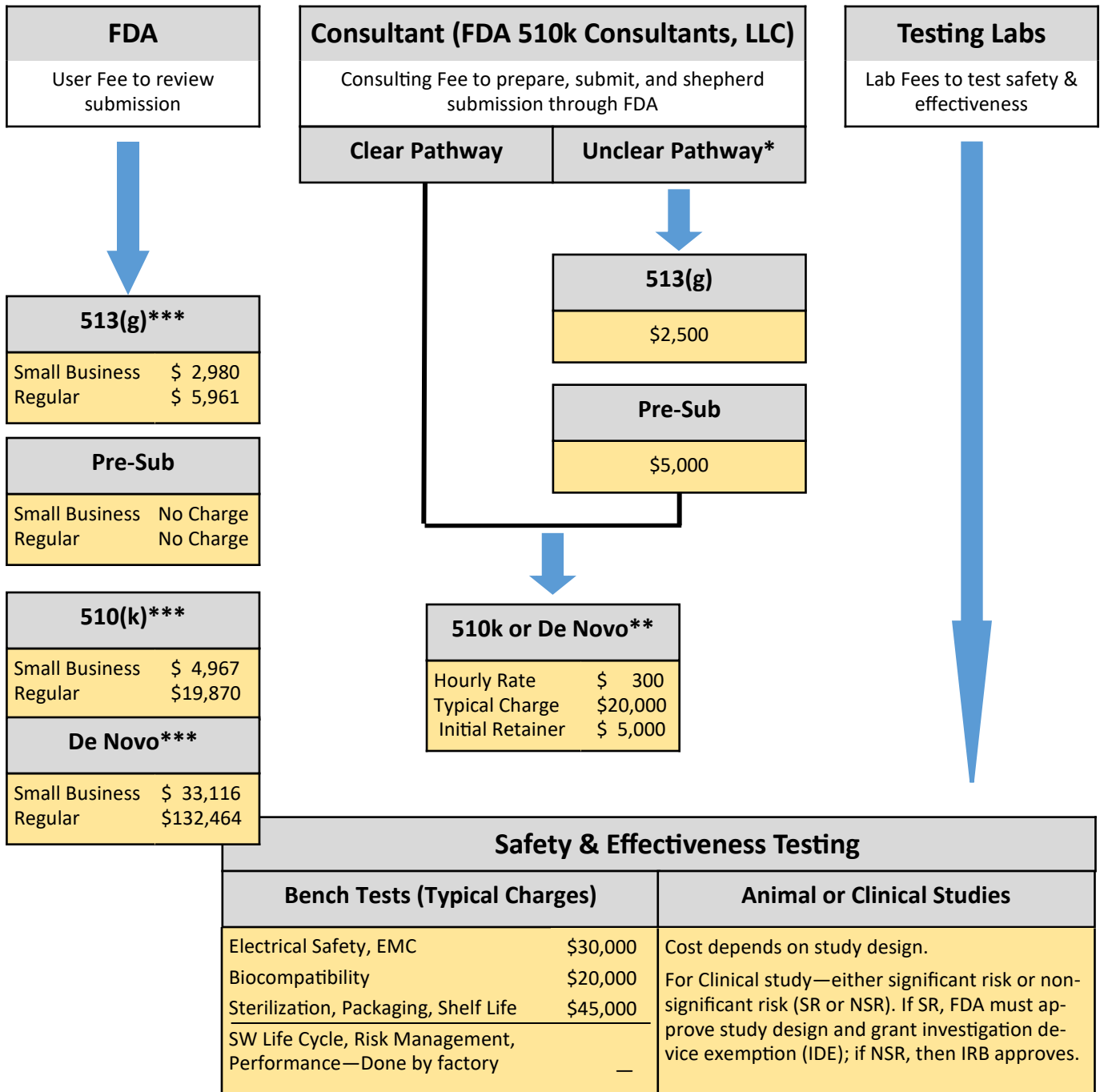


Medical Device Premarket Costs (510k, De Novo)



* - "Unclear pathway" usually means uncertainty about predicate selection or device testing.

** - Typical final consulting charge is \$20,000 to \$25,000 for devices with both clear regulatory pathway (familiar intended use and technology, good predicate, FDA-registered factory, S&E tests done) and cooperative client.

*** - Prices for fiscal year that runs from October 1, 2023, to September 30, 2024. To qualify as "small business," the firm's global consolidated annual sales cannot exceed \$100 million.