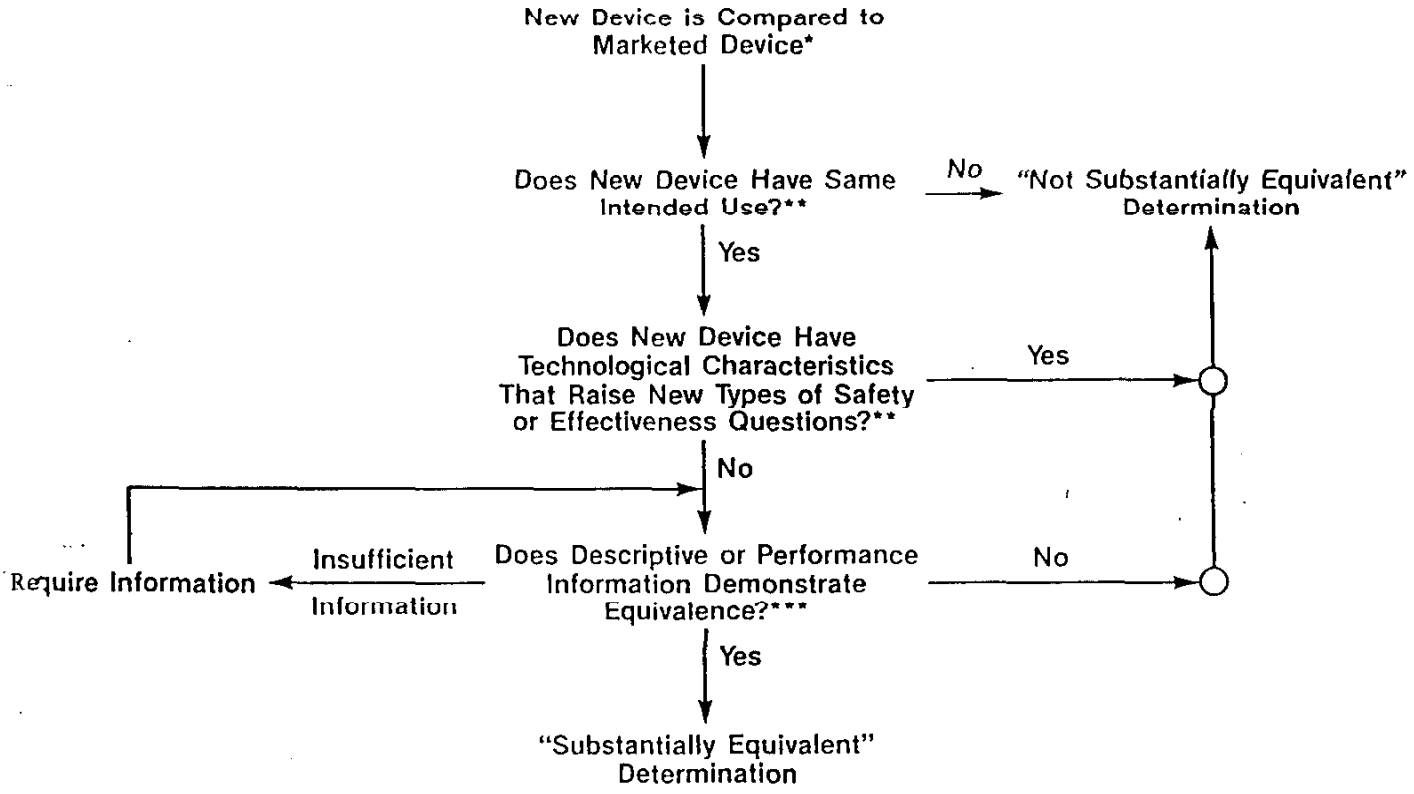
ATTACHMENT I

510(k) "Substantial Equivalence" Decision-Making Process (Overview)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information If the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Device is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.