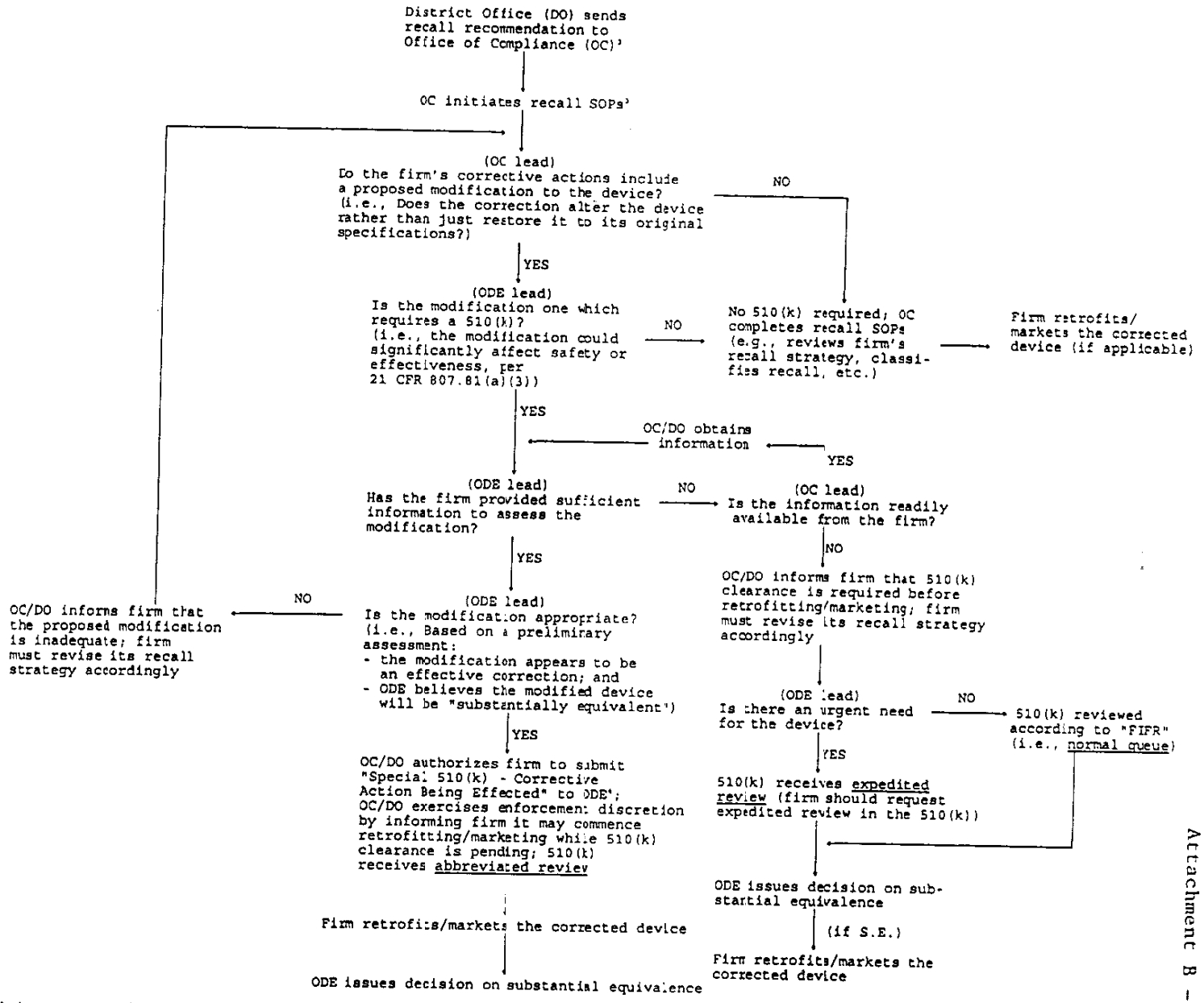
510(k) Requirements for Proposed "Fixes" to Devices Undergoing Recall[1]



[1] Applies to recalls involving a preamendments or "510(k)'ed" device that is legally marketed.
[2] In urgent situations, CDRH action is initiated before receipt of a formal recall recommendation.
[3] Includes assessing need for continued use of distributed devices, health hazard evaluation, etc.
[4] Firm must receive prior authorization from CDRH.