

Examples of Combination Products

1. Combination drug-device products:
 - a. chemoembolization devices (e.g., implantable spheres) that deliver chemotherapeutic drugs locally, and also block blood flow
 - b. catheters that deliver clot-busting drugs, and also act physically (through mechanical action or delivery of energy) to break up clots
 - c. spinal implant for structural purpose that also delivers drug to relieve pain in cases of spinal degeneration
 - d. closed loop insulin delivery systems (i.e., artificial pancreas) (where device function is critical to proper delivery of appropriate amount, over appropriate time period)

[For each of the above examples, how do the following additional variables affect assessments of primary mode of action?

- **what if the drug component is an old, generic, off-patent drug?**
- **what if the mode of administration and dosage of the drug are changed only slightly?**
- **what if the drug indication remains the same?**
- **what if only secondary aspects of drug labeling (e.g., precautions, instructions for use) change?]**

2. Combination device-biologic products:
 - a. spinal fusion products
 - b. porcine-derived protein matrices for periodontal repair
 - c. skin replacement products for wound healing containing cellular and/or extracellular components