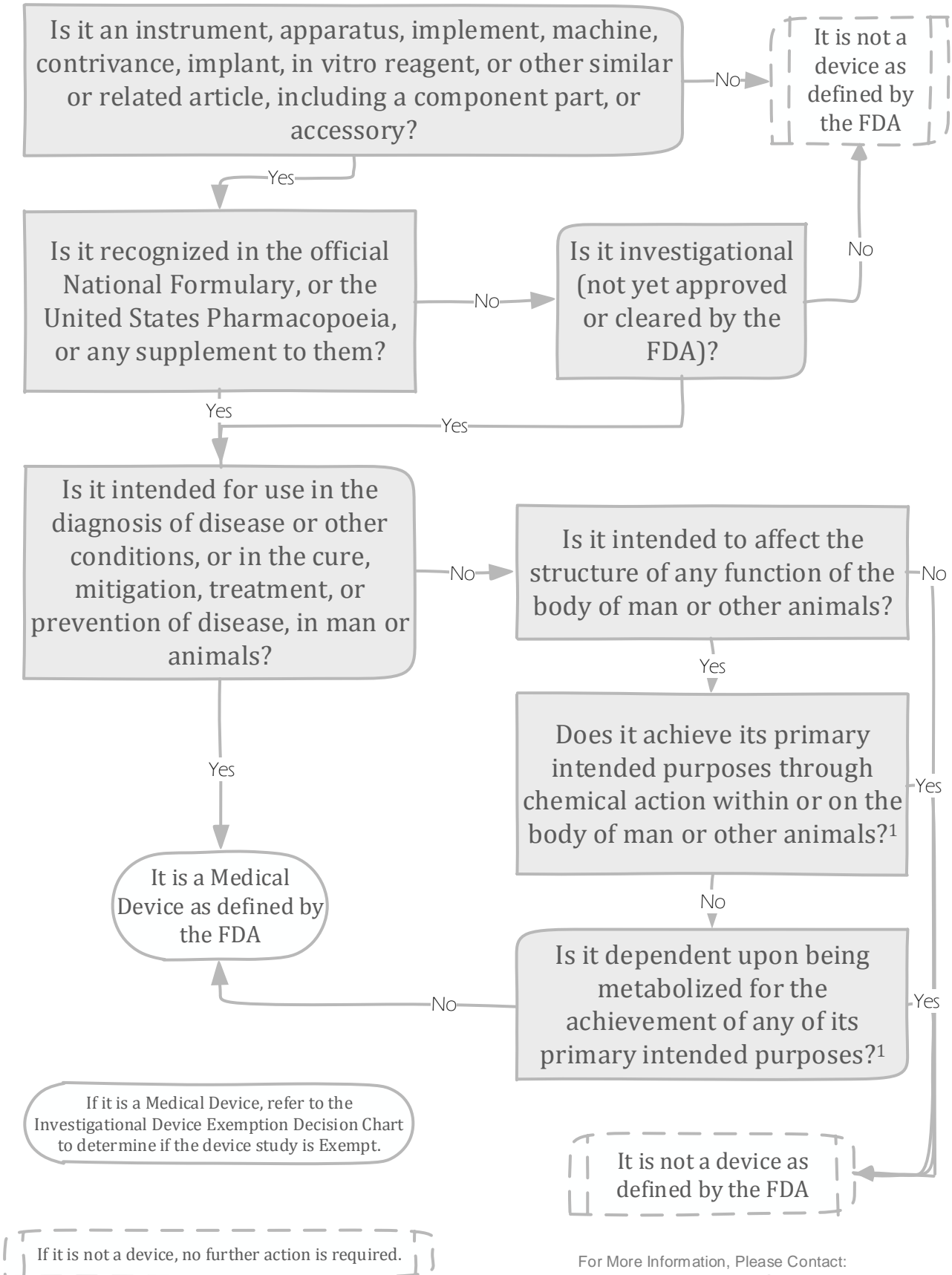


# Is it a Medical Device?

This document is intended to be guidance only and cannot replace a formal determination from the FDA.



If it is not a device, no further action is required.

<sup>1</sup> If Yes, it may not be a device as defined by the FDA, but it may be a drug and require an IND from the FDA. Please refer to the IND Decision Chart.

For More Information, Please Contact:  
**Human Research Protection Program**  
 Institutional Review Board  
 Office of Research Integrity  
 Phone: 541-737-8008  
 Email: IRB@oregonstate.edu  
 Website: oregonstate.edu/research/irb

