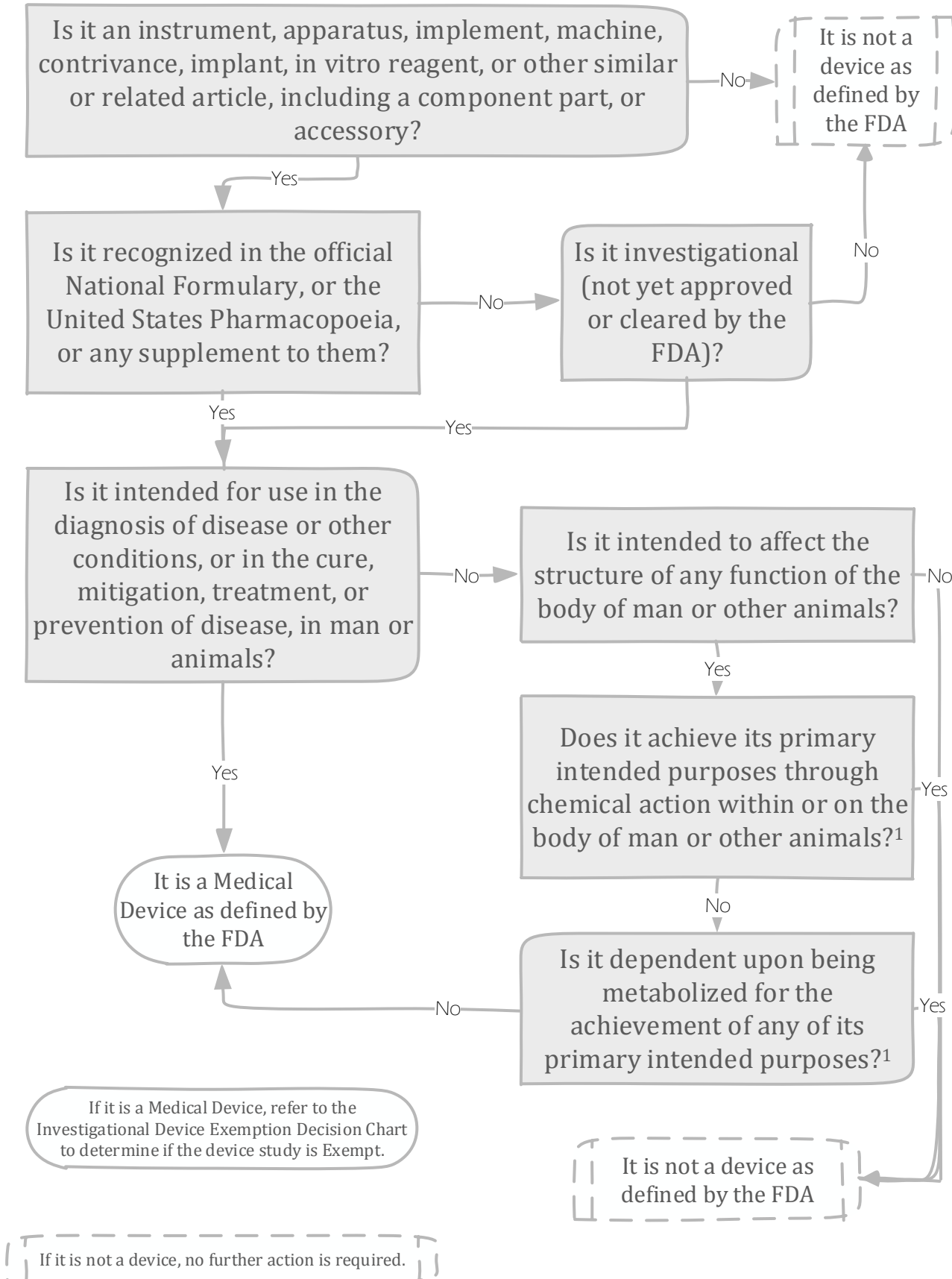


Is it a Medical Device?

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



¹ 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.