Is it a Medical Device?
This document is intended to be guidance only and cannot replace a formal determination from the FDA.

Is it an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory?

- Yes: Is it recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them?
  - Yes: Is it investigational (not yet approved or cleared by the FDA)?
    - Yes: Is it intended to affect the structure of any function of the body of man or other animals?
      - Yes: Does it achieve its primary intended purposes through chemical action within or on the body of man or other animals?
        - Yes: Is it dependent upon being metabolized for the achievement of any of its primary intended purposes?
          - Yes: It is not a device as defined by the FDA
          - No: It is a Medical Device as defined by the FDA
        - No: It is not a device as defined by the FDA
      - No: It is not a device as defined by the FDA
    - No: It is not a device as defined by the FDA
  - No: It is not a device as defined by the FDA

- No: It is not a device as defined by the FDA

If it is a Medical Device, refer to the Investigational Device Exemption Decision Chart to determine if the device study is Exempt.

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

1If 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:
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