AHVAP
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CERTIFICATION CENTER

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Medical Device Safety Checklist

1) Is the device FDA cleared or registered?
    a. Yes
    b. No, reconsider if use is appropriate.
2) Will the device be used on more than one-patient ?
    a. Yes
    b. No
3) What is the FDA classification of the medical device ?
    a. Class I
    b. Class II
    c. Class III
4) Does the medical device require reprocessing if it is reusable ?
    a. Yes
    b. No
5) If the answer to Question #4 is YES, then are reprocessing instructions available?
    a. Yes
    b. No
6) Has the device ever been recalled?
    a. Yes
    b. No
7) If the answer to Question #6 is YES, then why has the device been recalled?
8) Are their MAUDE reports related to the device ?
    a. Yes
    b. No
9) If the answer to Question #8 is YES, then describe the trends associated with the MAUDE reports.
10) What type of reprocessing does the device require according to the Spaulding Classification?
    a. Low/Intermediate-Level Disinfection
    b. High Level Disinfection
    c. Sterilization
11) What is the device's intended use as specified in the FDA approval?
12) How is the device packaged between uses (if reusable)?
13) What other devices/accessories (if any) will the device be used in conjunction with?
14) Who are the end users of the device?
15) What are the storage requirements for the device?
16) What maintenance is required to keep the device functioning safely ?
17) Does the device meet the criteria set forth by the FDA's Next Generation Medical Devices?
    a. Smooth surfaces, including smooth inner surfaces of the long, narrow interior channels (lumens)
    b. The ability to disassemble devices with multiple components
    c. Non-interchangeable connectors for critical connections (For example, tubes used with endoscopes for direct patient connection that cannot be interchanged with tubing used for waste drainage)
    d. Clear identification of connecting accessories, such as drainage tubing
    e. Clear indication and identification of components that must be discarded after patient use and cannot be reprocessed or reused
    f. Disposable components for the hardest to clean areas
    g. Designs that address how fluid flows through the device, and areas of debris build-up within devices