ORDB 510(K) STERILITY REVIEW GUIDANCE
7/3/97

For **STERILE** devices:

1. Provide the sterilization method that will be used or was used [radiation, steam, EtO].
   a. If the sterilization method is radiation, then provide the radiation dose that will be or was used.
   b. If the sterilization method is EtO, then provide the maximum residual levels of ethylene oxide, ethylene chlorohydrin and ethylene glycol that will be or were met. These levels must be below those limits proposed in FR 27482 (6/23/78).

2. Provide the Sterility Assurance Level (SAL) you intend to meet or met.

3. Identify the sterility validation method that will be used or was used.

4. Provide a statement of whether device will be or is "pyrogen free" and a description of the method used to make that determination.

5. Provide a description of the packaging used to maintain sterility.

6. Provide sample labeling that reflects the "sterile" notation.

For **NONSTERILE** devices which must be sterilized prior to use or for devices which a sponsor states in the 510(k) that they may be **RESTERILIZED**:

1. Identify a recommended set or sets of sterilization process parameters (for steam - the cycle, temperature, and exposure time; for EtO - temperature, humidity, gas concentration, exposure time, and aeration cycle).

2. Provide the Sterility Assurance Level (SAL) you intend to meet or met ($\leq 10^{-6}$).

3. Identify the sterility validation method that will be used or was used (e.g., AAMI).

4. If the sterilization method is EtO, then identify the maximum residual levels of ethylene oxide, ethylene chlorohydrin and ethylene glycol that will be or were met. These levels must be below those limits proposed in FR 27482 (6/23/78).

5. If provided nonsterile, provide sample package labeling that reflects some type of nonsterile notation.

6. Provide a sample package insert that reflects the sterilization process parameters.

If the process parameters have not been validated, then state that the validation will be completed prior to marketing and that the package insert will be revised to reflect the validated parameters.

For **REUSABLE** devices:

1. Provide cleaning recommendations including any applicable disassembly instructions.

2. Provide sterilization information following the applicable guidance(s) above.

3. For the labeling:
   a. Provide sample labeling with any recommended cleaning techniques and any applicable disassembly instructions.
   b. If the sterilization process parameters have already been validated, then provide sample labeling that includes the recommended sterilization process parameters. Otherwise, if the parameters have not been validated, then provide a statement that, prior to marketing, the package insert will be revised to include the validated sterilization process parameters.

d/t:SXN;HXS:11/18/94
d/t:SXN;SPR:1/17/96:clarify nonsterile portion
d/t:SXN:7/3/97:clarify nonsterile portion; make direct reference to resterilization