Introduction
Conventional sterilization methods have been well established in the medical device industry. Ethylene oxide is routinely used for gaseous sterilization of disposable healthcare products and medical device manufacturing. Its high penetration rate and potency of microbial kill proved to be an excellent technology for sterilization. However, ethylene oxide leaves harmful residues that are carcinogenic to humans; long aeration times are needed to make these products safe for human interaction. At the same time, such aeration times increase supply chain complexity.

Additionally, gamma radiation was introduced in industrial sterilization as a no-residual, safe alternative to ethylene oxide sterilization. However, due to its high penetration energy the process has a tendency to crosslink materials, particularly plastics.

Further, heat is often used with ethylene oxide sterilization, and radiation can also generate heat during the sterilization process. This causes problems with heat-sensitive devices. In summary, these limitations lengthen product development timelines due to additional sterilization trials and narrowed list of available materials that may fit into product design specifications.

Alternate Sterilization Selection Process
Alternate sterilization technologies emerge to address such limitations from conventional sterilization methods. These technologies, such as vaporized chemical sterilants, new forms of radiation, sound waves or high intensity lights, claim to have advantages in lower sterilization temperature, superior materials compatibility, and faster processing times with equal or better sterilization efficacy. The following checklist provides an objective assessment on the suitability for alternate sterilization methods for a particular application:

1. Efficacy
   ✓ Can the sterilization method achieve SAL $10^{-6}$?
   ✓ Is the entire product package (device and packaging) functional after sterilization?
   ✓ Are all materials tested compatible with sterilization method?

2. Regulatory
   ✓ Is there an established regulatory pathway for this sterilization method for the class of device?
   ✓ Does the product sterilization company have regulatory development know-how?
   ✓ Consult applicable ODE specialty branch if non-traditional or novel non-traditional technology is employed.

3. Operations
   ✓ What is the distance from your facility to the sterilization contractor?
   ✓ How much supply chain flexibility do you need for your operation?
   ✓ Is in-house sterilization installation an option for your supply chain?

4. Sterilization provider
   ✓ What is the commercial viability of the sterilization company in the next 3-5 years?
   ✓ How much support service does the company provide (e.g. testing services, protocol development, packaging assembly)?

5. Financial assessment
   ✓ How will this process provide cost advantages over conventional methods?
   ✓ How are the risks above weighted against the benefits (R&D, financial, supply chain) as a result of using alternate sterilization methods?

Conclusion
While conventional sterilization technologies are well established, alternate sterilization methodologies provide possibilities that were previously deemed impossible. It is up to the medical technology community to assess the risk/benefit trade-off. From this evaluation, one can make sound decisions that maximize the success of medical device development, while offering sterile products that are safe, cost-effective, and positively impact the healthcare industry.
Appendix: Decision tree for consideration in sterilization selection.