

### Adoption of a Safe Component

Your medical device startup company is developing a method to address a unmet need for therapy of a condition in the extremities. The therapeutic device is strapped to the leg or arm in your embodiment that was used in the clinical study. The strap itself is considered a class I exempt medical device. The strap is still subject to design controls but, as an accessory, it does not require FDA approval.

You have chosen an “off-the-shelf” strap. You do not have extensive information on this strap but you are aware that good clinical results were achieved by another device using this strap and it showed no problems during your clinical study. In preparation for market release of the product and attached strap, you decide to do some limited biocompatibility testing on this strap just to be thorough. Surprisingly, the strap fails one of the biocompatibility tests.

- What should you do now?
- What are the choices?
- You have a “frank and honest” discussion with the manufacturer of the strap pushing them on field issues that may have been reported to them about skin reaction to their straps.
- You analyze your own clinical data with regard to the strap.
- Your team decides to assess the relative danger to our prospective patients using a risk analysis based approach using the information you have gathered so far.
- At what level of risk are you willing to continue using the strap?
- What additional testing or strap modification is justified in your assessment?

The originator of this case suggested the following:

- Lesson Learned: When using off the shelf products, use a risk based approach for assessing the product. No testing is guaranteed to pass, so keep that in mind and think critically when creating a test plan. Actual clinical data trumps bench top or animal data, but patient safety should always be the first priority.