MEDICAL QA & REGULATORY AFFAIRS

Final Exam

Please complete the following study questions, and email to the Instructor (info@technologyed.com)

1. **Consider the following product**

Patient Warming for Virtually Any Procedure

Since its inception in 1987, 3M™ Bair Hugger™ therapy's forced-air warming technology has become a standard in hospitals around the world, safely warming 165+ million patients. With 170+ published studies documenting the clinical benefits of forced-air warming for maintaining normothermia and over 80% of U.S. hospitals utilizing Bair Hugger therapy, the numbers speak for themselves.

http://solutions.3m.com/wps/portal/3M/en_US/IPD-NA/3M-Infection-Prevention/products/catalog/?N=7570550&rt=c3

1. Briefly define and discuss the above medical device
2. Would this product be considered a Class I, II, or III medical device? Why?
3. Would you foresee any 510(k) submission challenges? Why?
4. Draft a brief example of the PMA Summary Section for this medical device
5. Briefly discuss GMP standards that would be required to manufacture such medical device
6. What would the registration and device listing be for this medical device? Why?