**BME 432 Biocompatibility, Final**

A company named “B-device” is planning to launch a series of products into the market (please see the list below). Regulatory bodies require that the products should be evaluated on biological safety tests and B-device is therefore looking for a consultant to screen its products to see whether they meet the requirements. As a biomedical engineer working in B-device, you are confident that you can set up a list of tests to screen the devices based on standards commonly referred to when testing biomaterials and/or biomedical devices. You feel that you will need to perform a thorough literature review including scientific publications, international standards, and reports published by regulatory institutions as well as private companies.

Your manager asks you to write a maxiumum of five-page report on each device (please choose only one for your assignment) to fit the following outline and expects a word document (single spaced, times new roman, font 11) to be emailed to cevaterisken@gmail.com with a due date of **xx/xx/2016 by midnight**:

1. Executive summary
2. Introduction
3. Structure, function, and composition of contact tissue/organ and **the mechanism of host response** in relevance to biocompatibility
4. Materials of construction of device
5. Type and duration of contact
6. Tests to evaluate material’s performance (provide information for each material, e.g, 5.1 Material X, 5.2 Material Y, etc.)
   1. Test1 (provide reference for the test procedure)
      1. In vitro/in vivo test procedure (if applicable, provide details as to whether the test will be performed using direct contact with or extract from the material, what type of cells can be used, what would serve as control, etc.)
      2. Criteria for success
      3. Tools and equipment needed to perform the tests (a list could be included in Appendix)
   2. Test 2
      1. In vitr /in vivo test procedure
      2. Criteria for success
      3. etc.
7. Limitations (provide information about the insufficiencies or absence of tests to evaluate the effect of material)
8. Conclusion
9. Appendix (include anything you feel necessary but cannot be included in the main body of the report because of the page limitation)

**Good luck!**

**List of devices:**

* Pacemaker
* Heart valves
* Dental implants
* Intervertebral discs
* Ocular implants
* Knee implants
* Cranial implants
* Sutures