Team_____ Date_____

FDA Homework
www.fda.gov

To do this assignment you may need to use the FDA website.

1) Determine what class your medical device is and describe why

2) Describe the step(s) you need to get your device approved by the FDA

   a. Is your device identical to another existing device?

   b. If so, what is the device?

   c. If so, is the device equivalent to another device?

   d. If so, what about is makes it equivalent?

   e. What process do you have to follow to get approval?

3) Determine if there were any recalls associated with devices similar to yours
   a. If so, does your design address these issues?
   b. If not, find a device similar to yours which has had recalls and address question 3) a.