NAME: FADARE R OMOTUNDE

Matric no: 16/ENG04/066

Course: Introduction to Biomedical Engineering EEE 578

Assignment Title: Ethics Legal and Societal Aspects Assignment

Question:
From the textbook by Madihallya: Principles of Biomedical Engineering. Assignment previously given in class; to be submitted via LMS.

INSTRCUTION: Answers are to be typewritten.

11.7 Your company is interested in selling their new pacemakers in Italy. Write the initial approach you would pursue in terms of whom you contact or what standards you would follow in obtaining the approval from the Italian government.

11.8 How many sections are in ISO 10993? List the number and corresponding title.

11.9 A new bioengineering company is interested in marketing a tissue-engineered skin product. They hired you to help them in determining the standards necessary for obtaining FDA approval. Provide three minimum standards they need to begin working on the FDA approval process.

11.10 You have developed a new prosthetic device for the hand. List the steps you would take to market this product in the United States, Europe, and Japan.

Answer:

11.7:

- As a manufacturer outside the European union, I will register with the Ministry of Health database and notify some technical data of the device, according to specific online forms for the purpose of their inclusion in the medical devices Repertoire.
- I will get the pacemakers CE marked.
- I will register the pacemakers with the Ministry of Health Directorate General for Medicines and Medical Devices using the National Health Information System (NSIS).
- I will make sure the pacemakers conform with the ISO 14708-2, IEC 601-1 and ISO 5841-1 standards.

11.8:

- 10993-1: "Guidance on Selection of Tests."
- 10993-2: "Animal Welfare Requirements."
- 10993-3: "Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity."
- 10993-4: "Selection of Tests for Interactions with Blood."
- 10993-5: "Tests for Cytotoxicity—In Vitro Methods."
- 10993-6: "Tests for Local Effects after Implantation."
- 10993-7: "Ethylene Oxide Sterilization Residuals."
- 10993-8: No title assigned.
- 10993-9: "Degradation of Materials Related to Biological Testing."
- 10993-10: "Tests for Irritation and Sensitization."
- 10993-11: "Tests for Systemic Toxicity."
- 10993-12: "Sample Preparation and Reference Materials."

11.9: minimum standards for a tissue engineered skin product for FDA approval

Cells;

1) Are minimally manipulated.
2) Are not combined with a drug or device.
3) Have no systemic effect and do not depend upon the metabolic activity of living cells for the primary function (except for autologous use or allogeneic use in a first-degree or second-degree blood relative).

11.10:

- I will check if the prosthetic device meets the international standards required and make modifications if need be.
- I will make sure the device complies with the local ethics (Religious and cultural) of the places where it would be marketed.
- I will make sure the device complies with the local regulatory bodies i.e FDA in the U.S.A, CENELEC in Europe, PMDA in Japan.
- I will make the clinical trials result public.
- I will supply samples to teaching hospitals and major distributors of medical devices.