**FAPOHUNDA OLUWATOMI OCHE**

**15/ENG04/025**

**EEE 578**

**ELECTRICAL/ ELECTRONICS ENGINEERING**

**QUESTION**

**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

**ANSWERS**

**11.7**

This is the initial approach I would pursue in terms of who I would contact or what standards I would follow in order to gain approval from the Italian government to sell my pacemakers in Italy.

* Since, pacemakers are to be implanted in the chest I would contact the medical community in Italy as to how the shape, size and leads of the pacemaker should be.
* Pacemakers are class III medical devices. That means regulations are going to be tighter because they are required to sustain human health and have an insurmountable potential to cause risk. I will ensure the equipment complies with general international organizations standards minimally such as, IEC 60601-1, ISO 10993 and the vertical standards such as the ISO 3826-4.
* I would also conform to the standards laid out by their national regulatory body the Comité Européen de Normalisation Electrotechnique (CENELEC, [www.cenelec.eu](http://www.cenelec.eu)) and any other local regulatory bodies while submitting the FDA’s equivalent of a PMA application. Also, pre-clinical and clinical trials will all be performed

**11.8**

There are 11 sections in ISO 10993 namely,

1. Evaluation and testing

2. Animal welfare requirements

3. Tests for genotoxicity, carcinogenicity, and reproductive toxicity

4. Selection of tests for interactions with blood

5. Tests for in vitro cytotoxicity

6. Tests for local effects after implantation

7. Ethylene oxide sterilization residuals

8. Degradation of materials related to biological testing

9. Tests for irritation and sensitization

10. Tests for systemic toxicity

11. Sample preparation and reference materials

**11.9**

Three minimum standards they need to begin working on the FDA approval process are (QSR) 21 of the Code of Federal Regulations (CFR) 820, (21 CFR Part 11) and 21 CFR 820.

**11.10**

The steps I would take to market the prosthetics in the US, Europe and Japan are;

* I would make my research on the cultural and ethical values on the product I ma marketing in the various countries
* I would ensure the products comply with any international standards necessary
* I would ensure the products comply with national regulatory bodies such as the FDA; the American National Standards Institute (ANSI, www.ansi.org); the American Society for Testing and Materials (ASTM, [www.astm.org](http://www.astm.org));the Comité Européen de Normalisation Electrotechnique (CENELEC, [www.cenelec.eu](http://www.cenelec.eu)); and the Japanese Industrial Standards Committee (JISC, [www.jisc.go.jp](http://www.jisc.go.jp)).
* FDA’s equivalent of PMA applications would be taken in each country if necessary
* Pre-clinical and clinical trials would be taken also