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Assignment on Ethics Legal and Societal Aspects

QUESTIONS

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 Initial approach I would pursue include:

- Contacting of the medical regulatory body in Italy to enquire about the medical, signal, economic and environmental factors to consider.
- I will check for the product's compliance to international standards for class III devices
- I will make sure the products conforms to regulations set by the regulated by the Ministry of Health Directorate General for Medicines and Medical Devices using the National Health Information System (NSIS) in Italy.
- The product should conform to standards set by CENELEC, Comité Européen de Normalisation Électrotechnique
- It should conform to specific standard such as EN 45502-2-2: 1998, EN 50527-2-1:2011 etc.

11.8 There are over 20 sections in ISO 10993

- ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- ISO 10993-2:2006 Biological evaluation of medical devices Part 2: Animal welfare requirements
- ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2017 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-6:2016 Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- ISO 10993-7:2008 Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
- ISO 10993-9:2010 Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products
- ISO 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2018 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials
- ISO 10993-13:2010 Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14:2009 Biological evaluation of medical devices Part 14: Identification and quantification of degradation products from ceramics
- ISO 10993-15:2009 Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-16:2018 Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables

- ISO 10993-17:2009 Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
- ISO/TS 10993-19:2006 Biological evaluation of medical devices Part 19: Physico-chemical, morphological and topographical characterization of materials
- ISO/TS 10993-20:2006 Biological evaluation of medical devices Part 20: Principles and methods for immunotoxicology testing of medical devices
- ISO/TR 10993-22:2017 Biological evaluation of medical devices Part 22: Guidance on nanomaterials

11.9 Minimum standards needed to begin working on FDA approval include the following:

- (QSR) 21 of the Code of Federal Regulations (CFR) 820
- 21 CFR part 11
- 21 CFR 1271

11.10 Steps I would take to market this product (prosthetic device for the hand) in the United States, Europe, and Japan.

- Research on the ethical values adopted in each country for biomedical devices
- Research on the influence of religion and culture on biomedical devices in the various countries
- Check of product's compliance to International standards and standard set and adopted by the target countries
- Check of product's compliance to regulatory bodies in the country
- Technical issues analysis
- Clinical use analysis