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15/ENG04/038

EEE 578: Introduction to Biomedical Engineering

ASSIGNMENT TITLE: Ethics Legal and Societal Aspects Assignment

11.7. Assuming my company is interested in selling our new pacemakers in Italy, our initial approach will be to contact the *Ministry of Health Directorate General for Medicines and Medical Devices.* Some of the standards we will take into consideration would be as follows;

I. ISO 13485 – This standard deals with the regulatory requirements for a quality management system. Its goal is to ensure that the safety and the quality of the device is taken into consideration and it certifies that the medical devices has met the safety and quality requirements.
II. IEC 60601-2-31 – This standard deals with the particular requirements for the basic safety and essential performance of pacemakers.

11.8. There are 21 sections in ISO 10993. They are;

I. ISO 10993-1:2018 – Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.
II. ISO 10993-2:2006 – Biological evaluation of medical devices Part 2: Animal welfare requirements
III. ISO 10993-3:2014 – Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
IV. ISO 10993-4:2017 – Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood
V. ISO 10993-5:2009 – Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.
VI. ISO 10993-6:2016 – Biological evaluation of medical devices Part 6: Tests for local effects after implantation
VII. ISO 10993-7:2008 – Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
VIII. ISO 10993-9:2010 – Biological evaluation of medical devices Part 9: Framework for identification and quantification of potential degradation products
IX. ISO 10993-10:2013 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
X. ISO 10993-11:2018 – Biological evaluation of medical devices Part 11: Tests for systemic toxicity
XI. ISO 10993-12:2012 – Biological evaluation of medical devices Part 12: Sample preparation and reference materials (available in English only)
XII. ISO 10993-13:2010 – Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices

XIII. ISO 10993-14:2009 – Biological evaluation of medical devices Part 14: Identification and quantification of degradation products from ceramics

XIV. ISO 10993-15:2009 – Biological evaluation of medical devices Part 15: Identification and quantification of degradation products from metals and alloys

XV. ISO 10993-16:2018 – Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables

XVI. ISO 10993-17:2009 – Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances

XVII. ISO 10993-18:2020 – Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process

XVIII. ISO/TS 10993-19:2006 – Biological evaluation of medical devices Part 19: Physico-chemical, morphological and topographical characterization of materials

XIX. ISO/TS 10993-20:2006 – Biological evaluation of medical devices Part 20: Principles and methods for immunotoxicology testing of medical devices

XX. ISO/TR 10993-22:2017 – Biological evaluation of medical devices Part 22: Guidance on nanomaterials.

XXI. ISO/TR 10993-33:2015 – Biological evaluation of medical devices Part 33: Guidance on tests to evaluate genotoxicity — Supplement to ISO 10993-3

11.9.

I. ISO 13485 – This standard deals with the regulatory requirements for a quality management system. Its goal is to ensure that the safety and the quality of the device is taken into consideration and it certifies that the medical devices has met the safety and quality requirements.

II. IEC 60601-2-31 – This standard deals with the particular requirements for the basic safety and essential performance of pacemakers.

III. ISO 10993-1:2018 – Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.

11.10. If I were to market the product in the UNITED STATES, I would;

I. Classify the device and understand applicable Regulatory Controls.

II. Select and prepare the correct Premarket Submission.

III. Send the Premarket submission to the FDA and interact with FDA staff during review.

IV. Comply with applicable Regulatory Controls including the establishment registration and device listing.

If I were to market the product in EUROPE, I would;

I. Determine the EU Medical Device Directive that applies to the device.
II. Classify the class of the device.
III. Implement ISO 13485 standard (Quality Management System).
IV. Prepare a technical file that provides detailed information on the medical device and its compliance with 93/42/EEC.
V. Appoint an Authorized Representative in Europe that is qualified to handle regulatory issues
VI. Prepare a Declaration of Conformity document that show that the device complies with the applicable Directive.
VII. Register the device with the Competent Authority.
VIII. Perform a Clinical Evaluation Report (CER) updates and Post-Market Surveillance (PMS) activities.

If I were to market the product in JAPAN, I would;

I. Determine the Regulatory pathway by finding out the device classification according to the Pharmaceutical Affairs Law (PAL) and the availability of the Japan Medical Device Nomenclature (JMDN code).
II. Appoint a local organization like MAH or D-MAH for the registration of the product, manufacturing facilities and creating bonding with Pharmaceuticals and Medical Devices Agency (PDMA).
III. Submit application to the PDMA for Foreign Manufacturer Accreditation.
IV. Implement a quality management system compliant with PAL & Ministry of Health, Labor and Welfare (MHLW).
V. Prepare and submit medical device certificate/approval to PDMA or a Registered Certified Body depending on the device classification.
VI. Conduct a Quality Management System audit.
VII. Finalize the certification process with the PDMA or the Registered Certified Body.

REFERENCES

11.100.20. (n.d.). ISO – International Organization for Standardization. https://www.iso.org/ics/11.100.20/x/

Europe CE marking regulatory process for medical devices. (2019, September 23). Emergo. https://www.emergobyul.com/resources/europe-process-chart

How to study and market your device. (2019, December 13). U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

ISO 13485 — Medical devices. (n.d.). ISO. https://www.iso.org/iso-13485-medical-devices.html

Japanese market of medical devices anup. (2016, October 27). Share and Discover Knowledge on

LinkedIn SlideShare. https://www.slideshare.net/Anupkumar283/japanese-market-of-medical-devices-anup