Regulations in Medical Devices

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Medical Device Classification System

- Classified into class I, II, and III according to the potential risk
- Class I : Notification Item
- Class II, III : Approval Item

Approval Procedure

- Review of Technical File
- Review of Safety and Effectiveness (if necessary)
- Type Testing
- Audit of Quality System

New Regulations in the medical devices

- Establishment of the guidance for clinic al trial procedure
- Establishment of the review guidance f or safety & effectiveness
- Implementation of technical file review by the third party

Clinical Trial Guidance

- Guidance of the clinical trial for medical d evice Dec 21, 2001.
- The guidance was established based on th e Helsinki Declaration.
- The function of Institutional Review Board was strengthened.
- Inspection by KFDA may be performed on the way clinical studies.

Safety & Effectiveness

- Review guidance for the safety & effective ness of medical device was revised to be harmonized with the international standar ds.
- Requirements of electrical safety and bioc ompatibility are in accordance with the int ernational standards.

Third Party Review

- The third party may review the technical f iles of class II medical devices which is d esignated by KFDA.
- The third party must be registered to KF DA in accordance with the guideline.

Thank You !

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