Recall issues in CIED

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Medical device recalls are initiated when a medical device is defective, poses a risk to health, or both. The medical device manufacturer is generally charged with voluntarily initiating a recall; however; if the manufacturer fails to act, regulatory authorities, such as the Food and Drug Administration ("FDA"), may directly initiate a recall.

Types of Medical Device Recalls (USA)

Class I. Dangerous or defective products that predictably could cause serious health problems or death.

Class II. Products that might cause a temporary health problem or that pose only a slight risk of a serious nature.

Class III. Products that are unlikely to cause any adverse health reaction but that violate FDA labeling or manufacturing laws.

Overview of Medical Device Regulations in Korea

■ Recalling Party - Manufacturer or importer

■ Recall Classification

▶Class 1 : Medical devices the use of which causes an incurable serious adverse side effect or death, or is likely to cause it;

▶Class 2 : Medical devices causing or likely to cause temporary or medical adverse side effects which are curable by use of medical devices; and

▶ Class 3 : Medical devices not conforming to the standard specifications under Article 18 of the Act, although a violative product is not likely to cause adverse health consequences.

■ Submission of recall action plan

▶Submitted to KFDA Headquarter

▶Time window from the date of such confirmation that a medical device falls under the subject of recall ;

- Within 5 days; Class 1
- Within 15 days : Class 2 & 3