IN-DEPTH ANALYSIS OF MEDICAL DEVICE RECALL

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ABSTRACT

This study analyzed 363 medical device recalls filed in 2010-2011. These medical device recalls were extracted from the monthly publications of the United States Food and Drug Administrations (US FDA). Each of the medical device recall was analyzed in terms of device type, cause of recall, and severity level. Approximately 31.4% (114 cases) of medical device recalls belonged to General and Plastics Surgery Devices. Significant association between device type and cause of recall indicated that mechanical defect had caused majority of recall in General and Plastics Surgery Devices (109 cases, 30%). These analytical findings provide a direction for conducting in-depth adverse events investigation. Thus not only engineering area (safety science) but also the hospital itself and medical researcher can use this study to derive new perspective or potential study to reduce the number of medical device problem.

Keywords: Medical device recall, classification, in-depth investigation