FDA 510(k) Review Times Improving, Annual Analysis Shows

Emergo Group

Review times for medical device 510(k) premarket notifications by the US Food and Drug Administration improved somewhat in 2011 after several years of lengthening review times, according to a new analysis of publically available FDA data by Emergo Group.

Most Class II devices and some Class I and III medical devices submitted for registration in the US are reviewed via the FDA's 510(k) Premarket Notification program before commercialization can begin.

Emergo Group's analysis covered 18,615 records pulled from the FDA website in January 2013. The full analysis can be viewed at http://www2.emergogroup.com/e/10582/fda-510k-review-times-research/24sslv/402436695 [1].

Emergo Group found that the number of 510(k) submissions cleared by the FDA within three months improved to 42% in 2011 from 40% in 2010. Average 510(k) review times also fell to 138 days in 2011 from 146 days in 2010. Chris Schorre, VP of Global Marketing notes: "FDA 510(k) review times had been steadily climbing since 2006, so it is encouraging to see that trend starting to reverse in 2011. Let's hope the trend continues." The analysis only look at 510(k) submissions received by the FDA through December 31, 2011 to allow at least one full year for those submissions to clear. Analysis showed that 95-97%of all cleared 510(k) submissions occur within one year of submission.

Other key findings:

- Half of all medical devices submitted for FDA 510(k) clearance fall under Orthopedic, Cardiovascular, General and Plastic Surgery, or Radiology categories.
- Radiological devices typically take the least amount of time to obtain 510(k) clearance (between 60 and 80 days), while clinical chemistry products such as blood glucose testing systems take the longest (180 days).

Although overall review time frames for 510(k) submissions remain higher than 2006-2009, these latest figures suggest that recent efforts to add resources and boost transparency at the FDA may be driving a more efficient medical device regulatory process in the US.

About Emergo Group

Emergo Group is an ISO registered medical device regulatory consulting [2] firm

with offices throughout North and South America, Europe, the Middle East and Asia. The firm has specific expertise in regulatory affairs, quality system compliance, clinical trial consulting, in-country representation and medical device distributor search consulting.

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