



# An analysis of FDA 510(k) data from 2006 through 2010



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## Purpose of the analysis was to determine:

1. Number of submissions the FDA clears each year.
2. How long it takes to get a 510(k) cleared and trends.
3. Percentage of 510(k) submissions by device category.
4. Percentage of 510(k) submissions that were Traditional, Special or Abbreviated.
5. Average “submission to clearance” time for 510(k) submissions reviewed internally by the FDA versus those done by a Third Party Reviewer.



## Analysis methodology:

Emergo Group performed an analysis of FDA 510(k) data downloaded from the FDA website on January 6, 2012. Data was pulled for the time period January 1, 2006 through December 31, 2010. Total number of records analyzed was 15,168. All data was sorted by the date FDA **received** a 510(k) submission, not the date it was cleared. Thus, 2008 data, for example, shows the statistics for all 510(k) submissions received by FDA between January 1, 2008 and December 31, 2008.

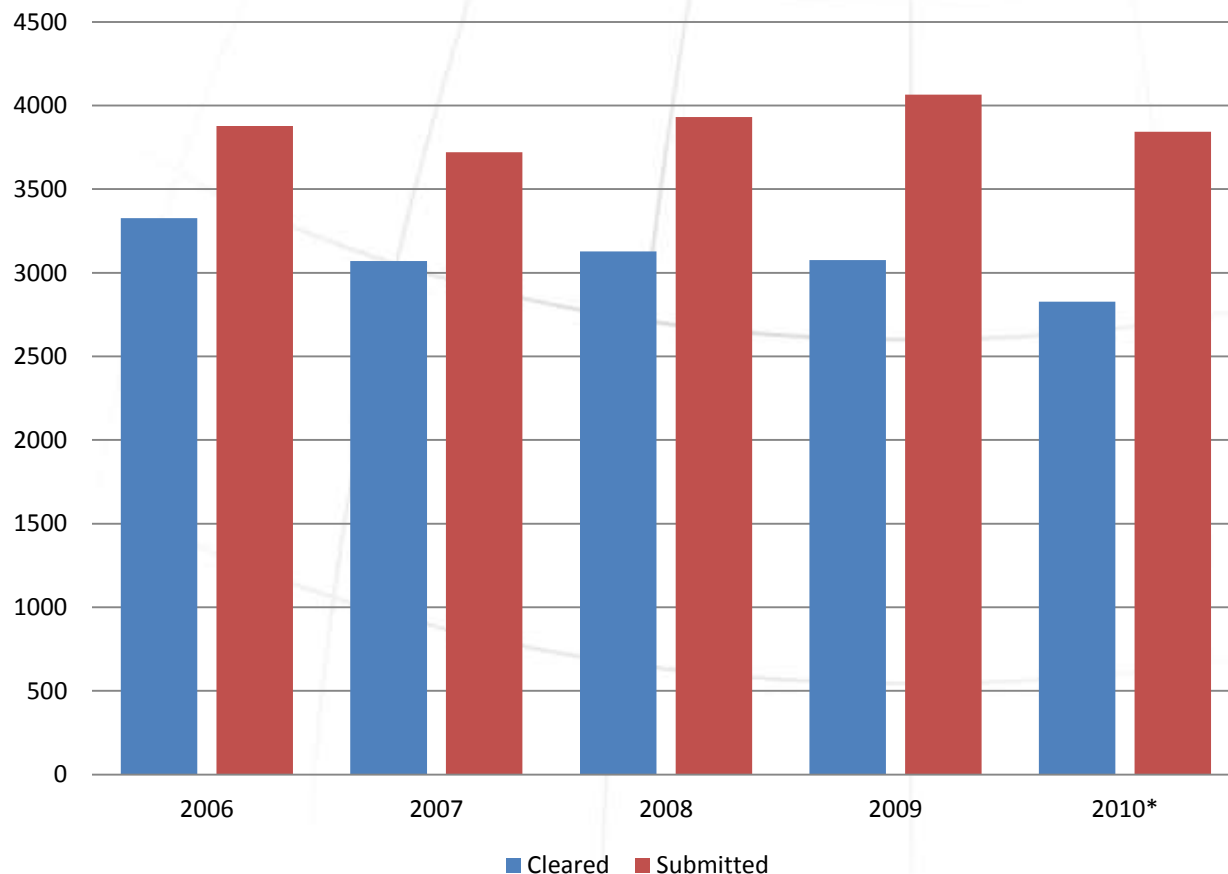
We only analyzed data for 510(k) submissions through the end of 2010 to allow a full 12 months for FDA 510(k) submissions to be cleared. Our analysis has shown that 95-97% of all 510(k) applications cleared by the FDA occur within one year of initial submission.

If you have questions about this analysis, please contact:

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# 510(k) submissions submitted and cleared by FDA



## Number cleared:

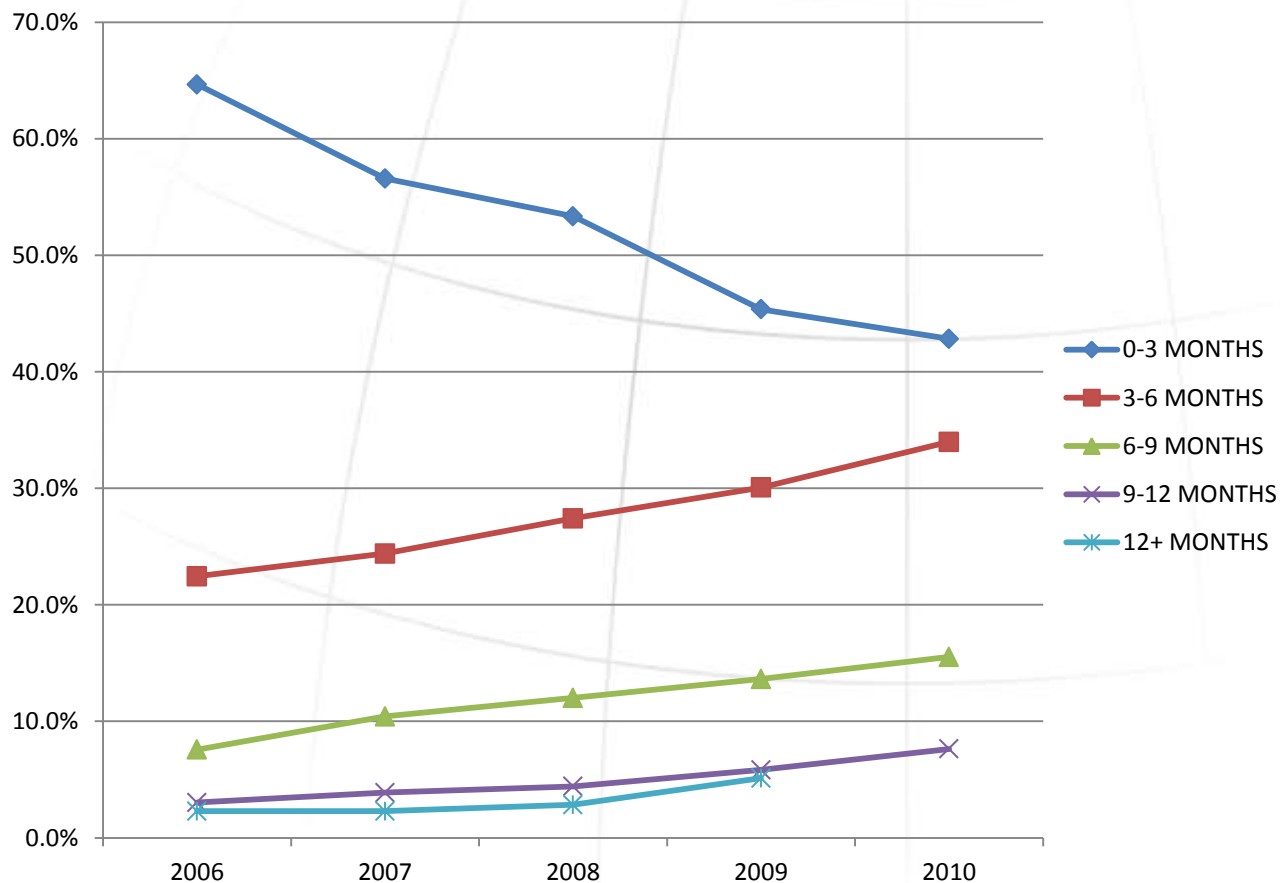
2006 – 3327/3877 = 85.8%  
2007 – 3069/3720 = 82.5%  
2008 – 3128/3931 = 79.6%  
2009 – 3076/4064 = 75.7%  
2010\* – 2826/3842 = 73.6%

## Comments:

The percentage of FDA 510(k) submissions cleared by the FDA has dropped steadily in recent years.

\* Numbers for 2010 may rise by as much as 5% as submissions received by FDA in late 2010 are cleared by FDA in early 2012. Based on historical analysis, 95%-97% of cleared submissions happen within 12 months of submission to the FDA.

# Average time for 510(k) submissions to clear.



## Average number of days:

2006 - 96 days  
 2007 - 110 days  
 2008 - 115 days  
 2009 - 133 days  
 2010 - 135 days

## Comments:

At first glance, the data seems to indicate that the FDA is taking longer to render 510(k) decisions. However, the lengthening time to clearance may reflect FDA reviewers more closely scrutinizing submitted data and asking more questions of submitters during the review process. This would lengthen the time from submission to clearance as the submitter would be required to address these issues raised by the FDA reviewer.



# Clearance time by device type.

Category of device	Average "submission to clearance" time in days	Percent of all 510(k) cleared devices
Anesthesiology	140	5.5%
Cardiovascular	103	11.9%
Clinical Chemistry	138	5.2%
Dental	113	8.9%
Ear, Nose, & Throat	104	1.0%
Gastroenterology & Urology	126	4.4%
General Hospital	114	8.6%
Hematology	161	1.4%
Immunology	182	1.6%
Microbiology	133	2.4%
Neurology	144	3.6%
Obstetrics/Gynecology	169	1.9%
Ophthalmic	149	1.8%
Orthopedic	111	15.4%
Pathology	173	0.2%
Physical Medicine	115	2.7%
Radiology	72	10.4%
General & Plastic Surgery	114	11.8%
Clinical Toxicology	179	1.3%

## Comments:

Emergo Group analyze data on 15,168 cleared medical devices submitted to the FDA between January 1, 2006 and December 31, 2010 and sorted them by Medical Specialty Code.

Not surprisingly, products in the pathology, immunology, ObGyn, toxicology and hematology categories took longest to clear.

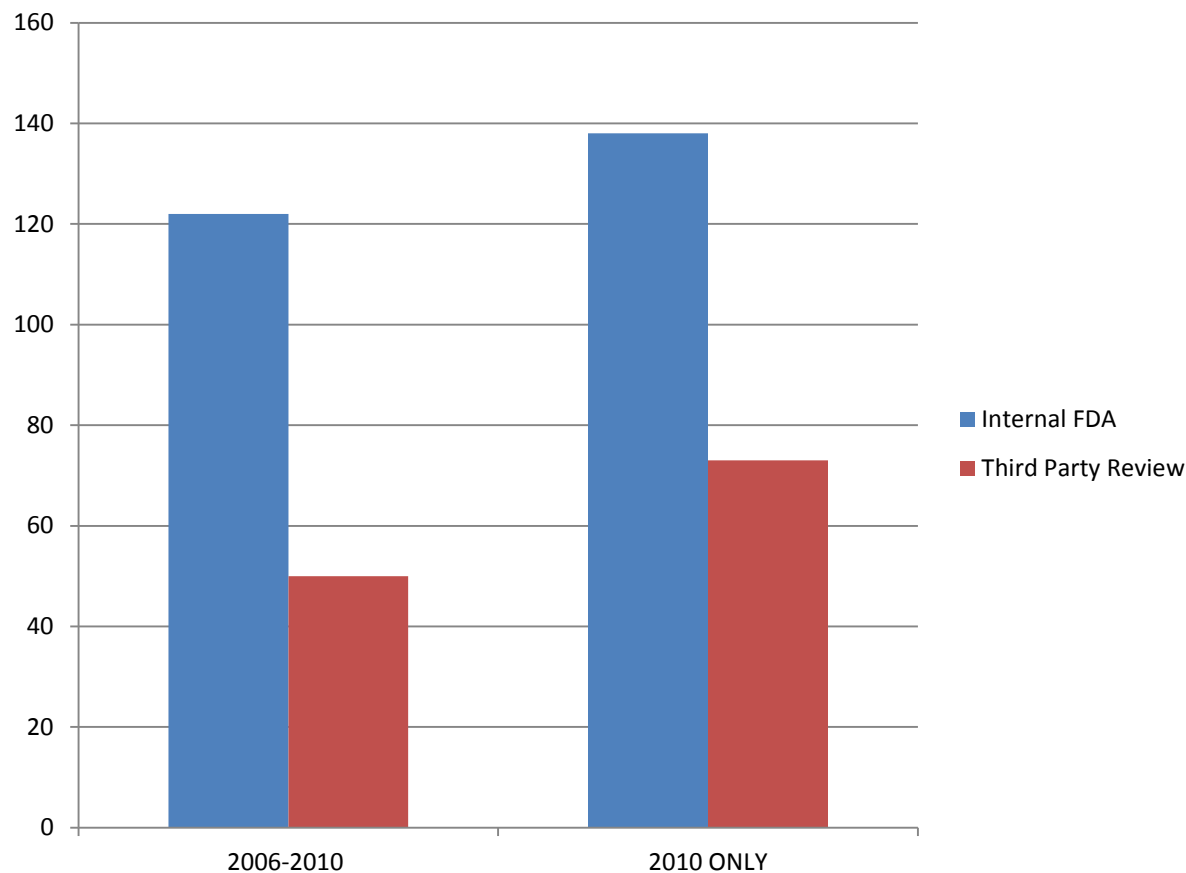
On average, radiology products took significantly less time to obtain Premarket Notification clearance.

Half of all products submitted for 510(k) clearance by FDA fall into these four categories:

- Orthopedic
- Cardiovascular
- General/Plastic Surgery
- Radiology



# Average 510(k) clearance time: Internal FDA versus Third Party Review.



**510(k) clearance time average for 2006-2010:**  
Internal FDA - 120 days  
Third Party - 50 days

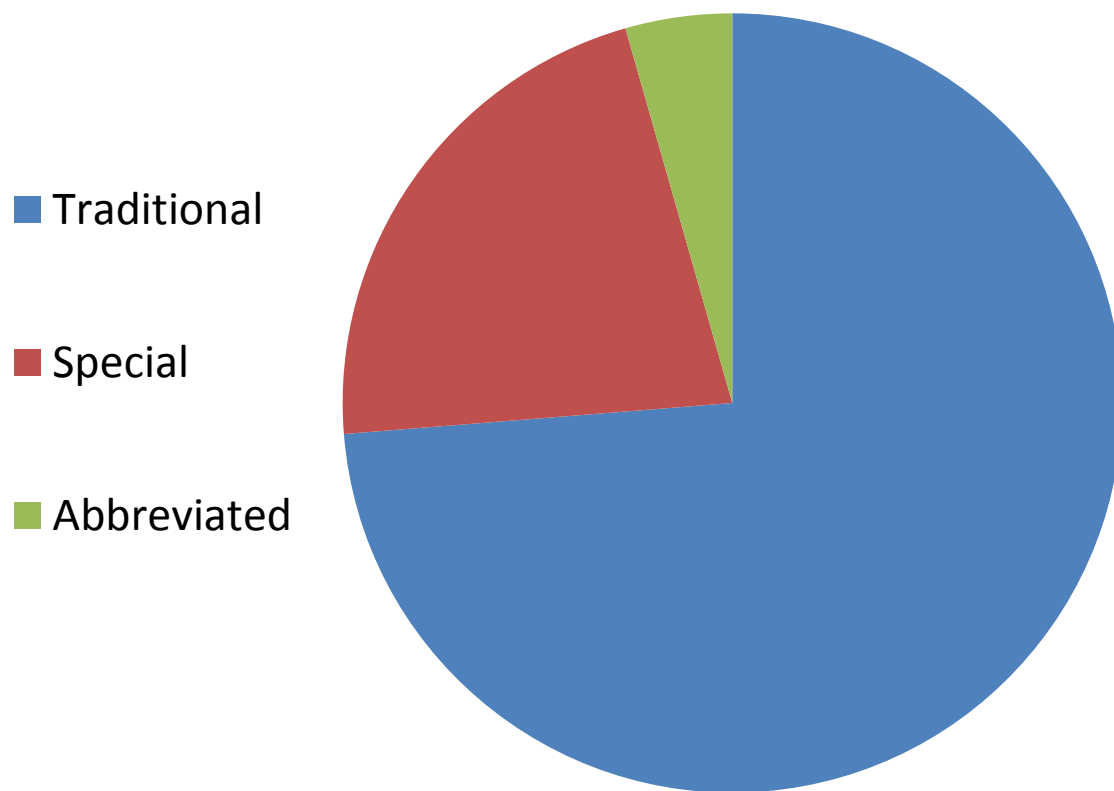
\* Based on analysis of FDA data of cleared medical devices from 2006 to 2010. Indicates the time from date of 510(k) submission to date of clearance by FDA.

## Comments:

Not all medical devices qualify for the FDA's Third Party Review program. However, companies in a hurry to commercialize their product may find this program beneficial. Note that for 2010, the ratio was 138 days (Internal FDA) to 73 days (Third Party Review). Fewer than 10% of devices go through the Third Party Review process.



## FDA 510(k) submission by type: 2006-2010.



### Type of 510(k):

Traditional – 74%

Special – 22%

Abbreviated - 4%

These numbers have remained relatively constant from 2006-2010.

Based on analysis of 15,168 cleared 510(k) submissions from January 1, 2006 to December 31, 2010.



## Additional resources:

Official US FDA medical device regulations

<http://www.emergogroup.com/resources/regulations-united-states>

US FDA regulatory process video (7 minutes)

<http://www.emergogroup.com/resources/videos-us-fda-regulatory-process>

US medical device regulatory process chart (PDF)

<http://www.emergogroup.com/literature>

FDA consulting services for medical devices

<http://www.emergogroup.com/services/us>

QA/RA blog with medical device regulatory updates

<http://www.emergogroup.com/blog>

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