How long it takes the US FDA to clear medical devices via the 510(k) process

An examination of 15,000 medical device applications cleared by the US Food and Drug Administration between 2012 and 2016.

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www.EmergoGroup.com
Executive Summary

Dear Reader:

Every year Emergo examines published data on medical devices cleared by the US Food and Drug Administration (FDA). The 15,000+ device clearances we analyzed went through the FDA’s Premarket Notification program, more commonly known as the 510(k). This process applies to nearly all Class 2 devices, and less than 10% of Class 1 devices. We sorted all devices based on the date they were cleared by FDA, not the date they were submitted.

The intent of this analysis is to examine how long it took medical device manufacturers to get devices cleared by US FDA last year, look at trends and see which countries are submitting the most applications.

Throughout the analysis you will see references to “clearing” devices. Technically, the FDA does not “approve” medical devices for sale via the 510(k) process – they “clear” them for sale in the US. Thus, the term “clearance” is essentially synonymous with approval.

As always, we welcome your feedback on this report.

Regards,

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Be sure to try our FDA 510(k) calculator, which shows the average review time for specific devices cleared in the last five years.
All FDA 510(k) submissions cleared - Traditional, Special, Abbreviated

Overall, the number of 510(k) submissions cleared in the US fell slightly in 2016. This represents the fewest number of devices cleared by the FDA since 2010 when roughly 2,800 devices were cleared. The decline is entirely attributable to fewer American companies submitting devices to the FDA, a decline which has been significant in 2015 and 2016 (see page 9).

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Bar chart showing the number of 510(k) submissions cleared from 2012 to 2016:
- 2012: 3138
- 2013: 3054
- 2014: 3203
- 2015: 3025
- 2016: 2957
Number of traditional 510(k) submissions cleared by FDA internal reviewers over time

The 510(k) process started in mid-1976 and it took several years for the FDA to “ramp up.” Starting around 1980s and continuing for another 10 years, volume increased markedly. Volume tapered off in the late 1990s and has since leveled off. However, the average time to obtain clearance continues a gradual upward march.
Number of calendar days from submission to FDA clearance – Traditional 510(k) only

Many industry veterans long for a return to the days when you could get a traditional 510(k) cleared within 100 days. It still happens, but far less frequently than it did in the early 2000s. The FDA – like many other regulatory authorities - has become much more strict about clinical evidence and testing requirements, thus lengthening the overall path to clearance. Most companies can plan on waiting about six months to get the green light from FDA, although that varies by device (see page 8). Companies willing and able to utilize Third Party Reviewers can get to market about four months faster on average.
Calendar days from submission to FDA clearance – Abbreviated and Special 510(k) only

Despite their name, Abbreviated 510(k) submissions tend to take as long, or longer, to get cleared by the FDA. That probably explains why only 3% of all 510(k) submissions go through the “Abbreviated” process. Companies can choose to submit an abbreviated 510(k) when guidance documents exist, a special control has been established or the FDA has recognized a relevant consensus standard.

Special 510(k) submissions, on the other hand, are processed fairly quickly. The Special 510(k) is used when a modification has been made to a device. It allows the manufacturer to declare conformity with the Design Controls requirements of the Quality System Regulation (21 CFR Part 820) but not provide the supporting data.
Percent of devices cleared within 3, 6, 9 and 12 months

As seen previously, the overall time to get a traditional 510(k) cleared has remained fairly steady over the last five years. Nonetheless, your chances of getting clearance within three months has diminished somewhat since 2012. Clearance times do vary significantly by device category. See page 8 for details.
Average calendar days from submission to clearance, by medical device type

As shown on page 5, companies waited 177 calendar days (about six months) on average for their device to get cleared by FDA during 2016. However, timeframes vary significantly by category of device. As might be expected, devices related to anesthesiology, immunology and hematology take considerably longer to get cleared whereas radiology devices tend to have a much shorter route to market.
Huge increase in submissions from non-US companies

Starting in 2015, a significant shift started to occur in the number of non-US companies submitting 510(k) applications to the FDA. To be clear, the data should not be construed to mean that most 510(k) submissions are made by US companies. Many larger foreign medical device companies have US subsidiaries that submit applications on their behalf.

Nonetheless, the data shows that 510(k) submissions from Asian and European companies has nearly doubled in the last two years. Why? Some of the increase can be attributed to the strong US Dollar which makes imported medical devices cheaper for US buyers. The exchange rate really started to shift in September 2014, encouraging many European and Asian companies to enter the US market in 2015 and 2016 knowing they would be in a better position to compete with US companies. During the past two years, significant increases in the overall number of 510(k) submissions were seen from firms located in Germany, Italy, Switzerland, China, Japan and South Korea.

The increase in submissions from Chinese manufacturers has less to do with currency rates and more to do with the fact that they are becoming more sophisticated and export savvy. The upward trend has been steady for several years and Chinese device companies continue to introduce more devices to the US market than any other country.

Share of all 510(k) submissions submitted by companies located in specific countries in 2016

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<thead>
<tr>
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<tbody>
<tr>
<td>Canada</td>
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<td>1.3%</td>
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<td>Japan</td>
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<td>Taiwan</td>
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<tr>
<td>UK</td>
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<tr>
<td>USA</td>
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<td>63.3%</td>
<td>59.7%</td>
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Fun FDA 510(k) Facts

Number of devices cleared via FDA 510(k) process since 1976

142,000

Number of devices cleared via FDA each year, give or take 10%

3,000

Did You know?

All 510(k) submissions are assigned a “K number” – the letter K followed by six digits. The first two digits of the 510(k) number indicate the year it was submitted to FDA for review. The next four digits are sequential starting at 0 and indicate the order in which the submission was received during the year. The first 510(k) ever was submitted by Zimmer Inc. which holds K760001, submitted on May 26, 1976. Boston Scientific Scimed Inc. is the proud owner of K000001. No, it’s not the first 510(k) ever, but it was the first one submitted in the new millennium on January 3, 2000! Many others were submitted that same day but theirs made it to the top of the pile.
Learn more about the FDA 510(k) process
If you would like to learn more about how the 510(k) process works, or how Emergo can help, just follow the links provided below.