

# EYE ON THE FDA

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## EXECUTIVE SUMMARY

Medical device companies' regulatory pathways are already longer than they were 10 years ago, despite the fact that the total number of devices submitted for approval to the U.S. Food and Drug Administration has declined almost 20 percent since 1998.

Taking into account a new, more stringent approach on the part of the FDA's new leadership and a comprehensive institutional examination of the 510(k) process that will likely result in recommendations for change, the regulatory path for new devices is likely to become longer, more costly and more onerous in the near future.

Furthermore, the types of devices being brought to market has converged over the past 10 years into three major sectors, increasing competition for the highest-cost markets, while almost every other type of device approval has declined significantly since 1998.

This report analyzes FDA approvals of medical devices for the 510(k) track from 1998 to 2009, parsed according to medical discipline, approval times and a variety of other categories. The report endeavors to:

- Characterize changes in the number of 510(k) approvals and decision times over the past decade through the first half of 2009;
- Identify the most active medical disciplines and states, in terms of 510(k) approvals;
- Provide perspectives on approval trends and developments in the regulatory landscape.

## STATISTICAL HIGHLIGHTS:

- In the first half of 2009, the FDA granted 1,519 510(k) approvals, up 1.7 percent from the same period in 2008 (see Figure 1, page 8)
- The average decision time during that period was 117 days, compared to 114 days during the first six months of 2008 (see Figure 7, page 11)
- General & Plastic Surgery (SU), Orthopedics (OR) and Cardiovascular (CV) were the three most active disciplines in receiving approvals (see Figure E, page 7, for a list of FDA discipline codes)
- The total number of approvals decreased from 3,777 in 1998 to 3,049 in 2008 (see Figure 4, page 9)
- Decision times rose slightly over the past decade, from 111 days in 1998 to 113 days in 2008 (see Figure 9, page 12)
- California, Massachusetts and New Jersey were the three most active regions, in terms of total number of approvals, during the past decade (see Figure 16, page 15).