

510(k) Benchmarking Survey

Nancy Singer &
Jim Dietrich
Compliance-Alliance.com
Nancy_Singer@juno.com



Dan Olivier
Certified Compliance Solutions
certifiedcompliance.com
doliver@certifiedcompliance.com

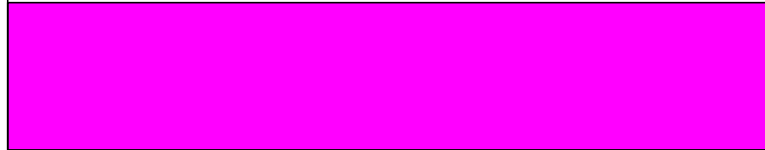


Demographics

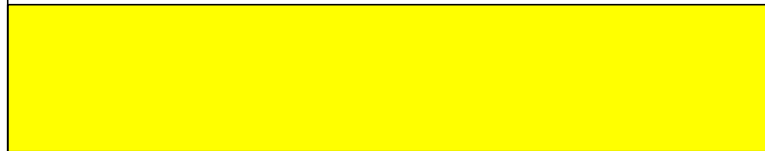
- Survey conducted June 2008
- 20 respondents in Clinical Chemistry and Clinical Toxicology Devices
- Large, medium and small firms were represented

Color Legend

**Significant
Majority**



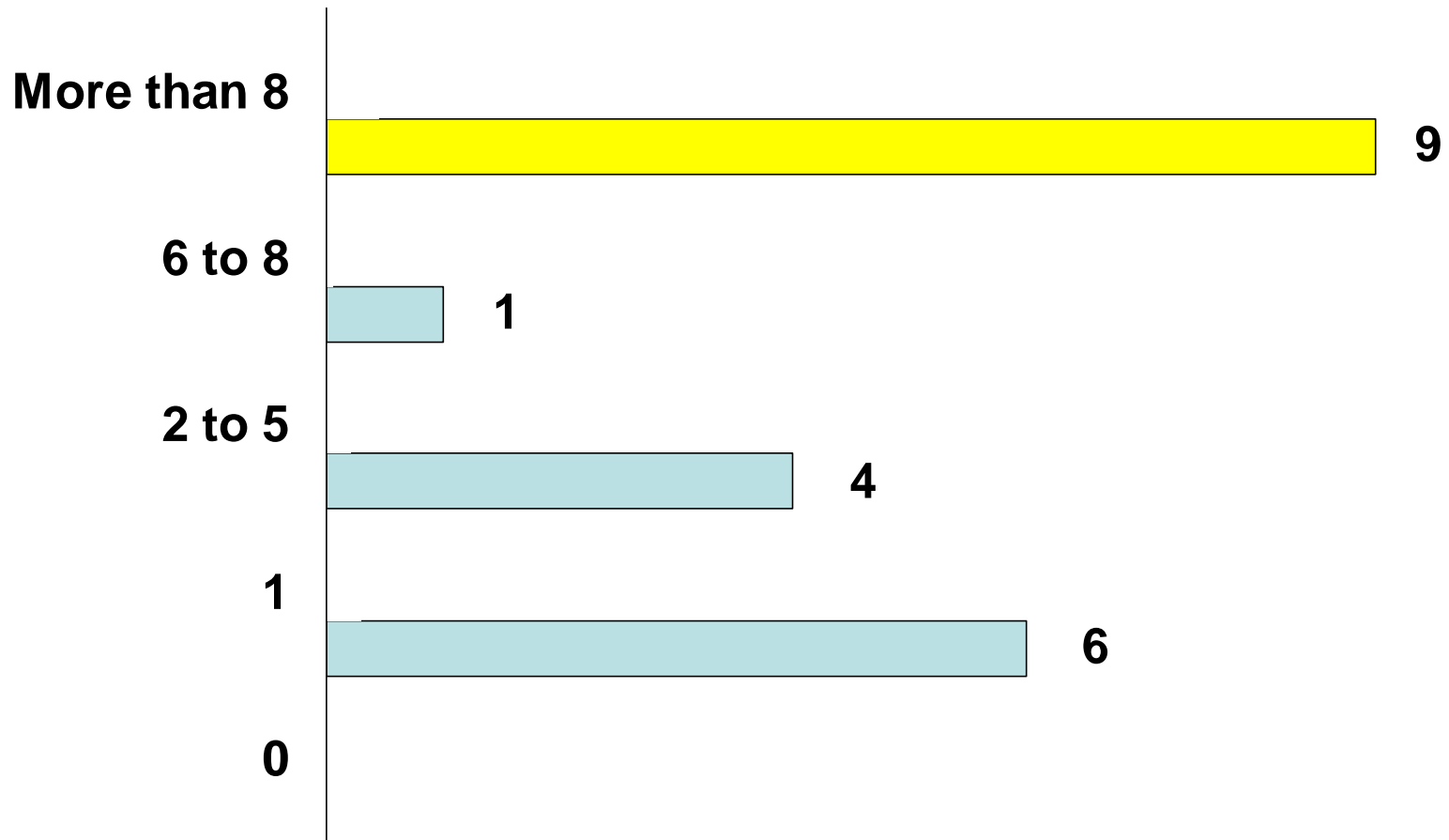
**Moderately
Significant**



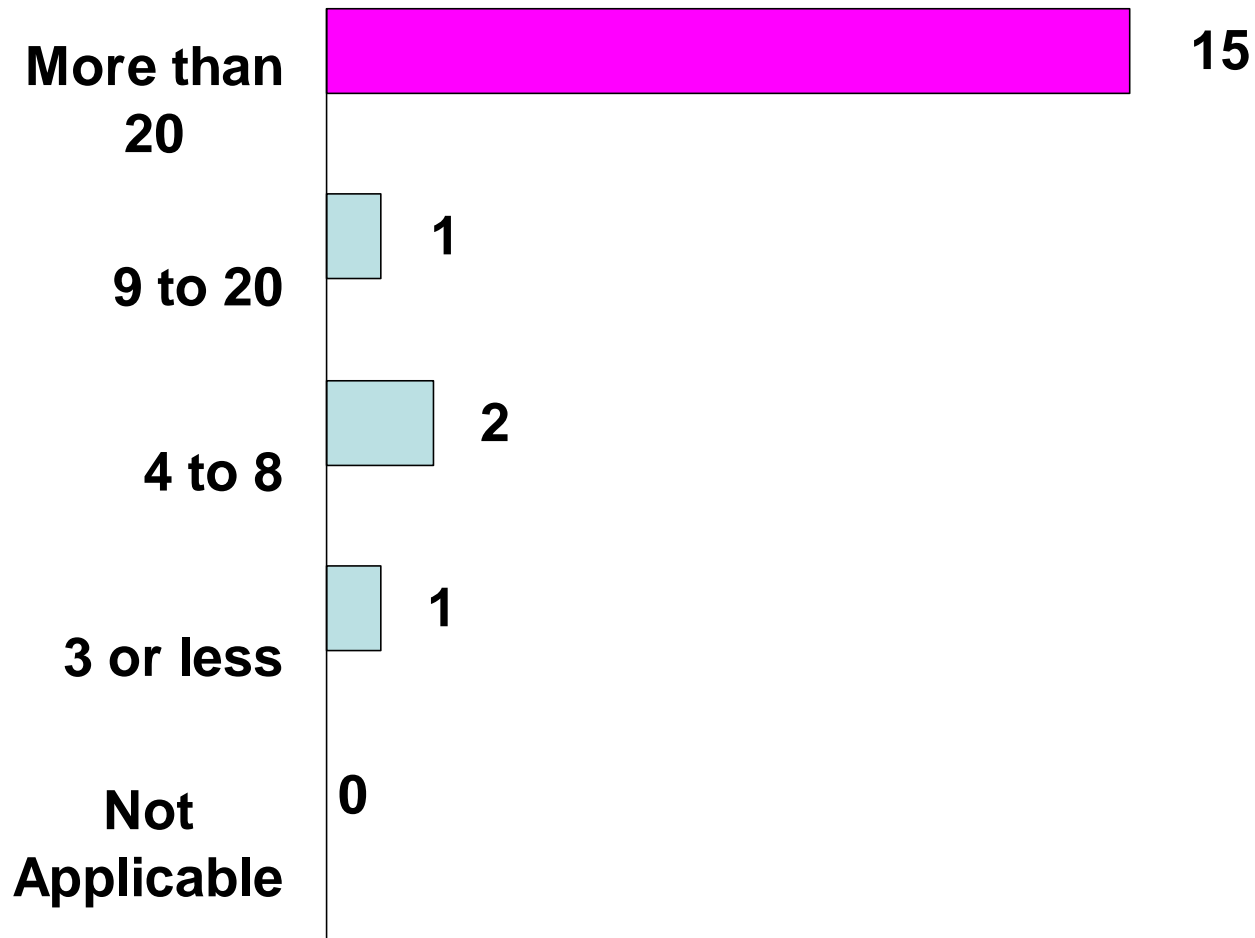
**Least
Chosen
Answers**



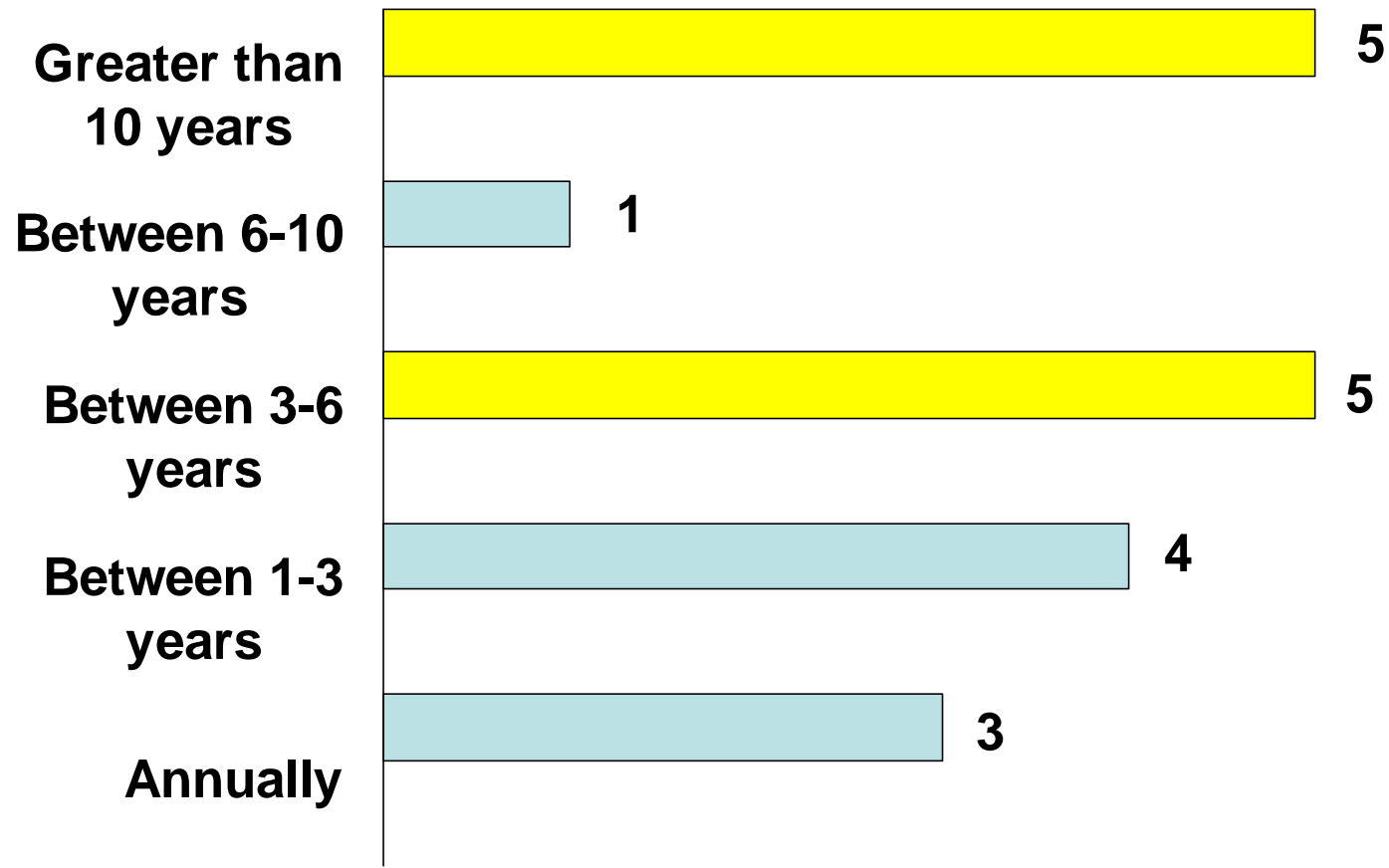
Number of 510(k)s Submitted Annually



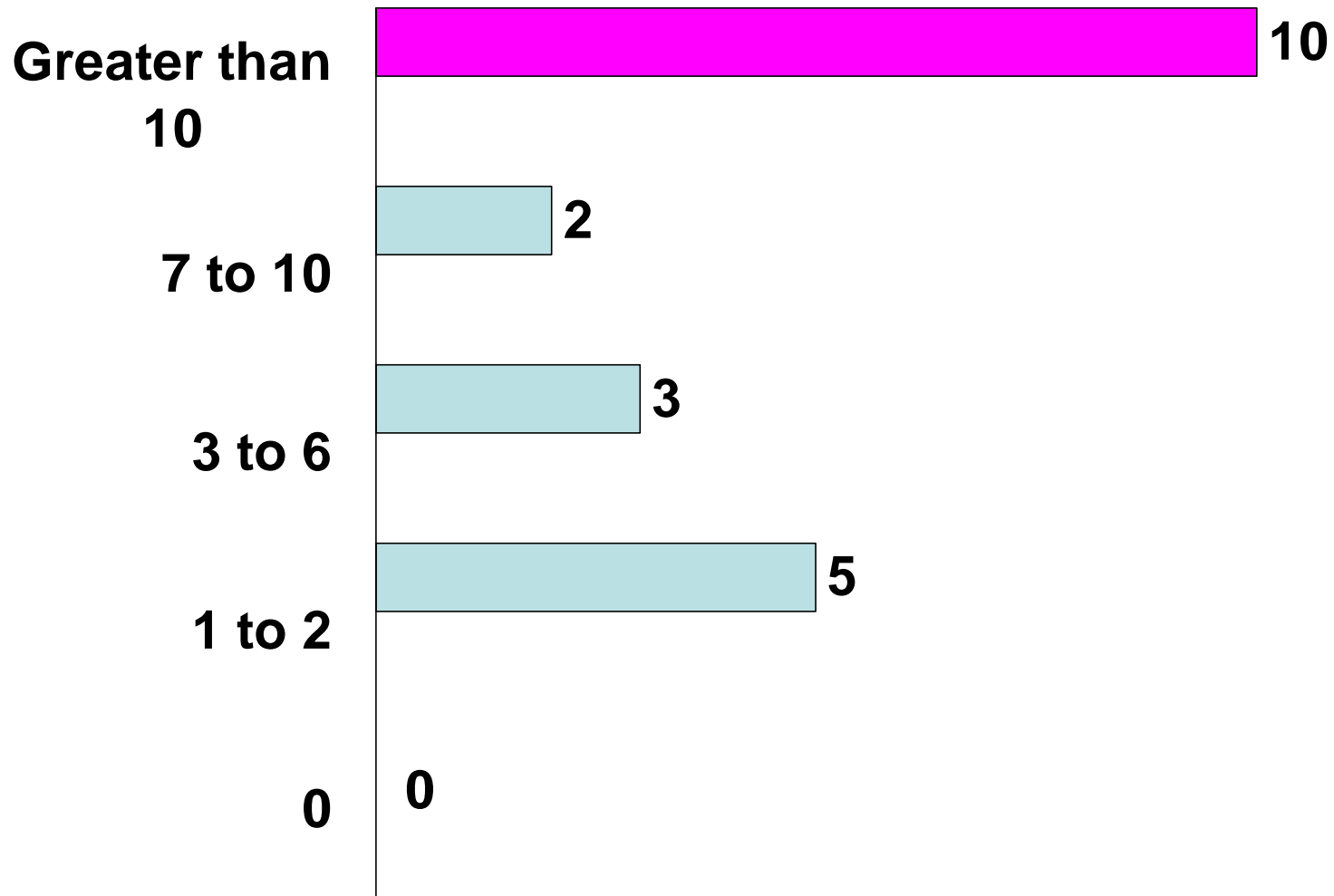
Number of 510(k)s Cleared



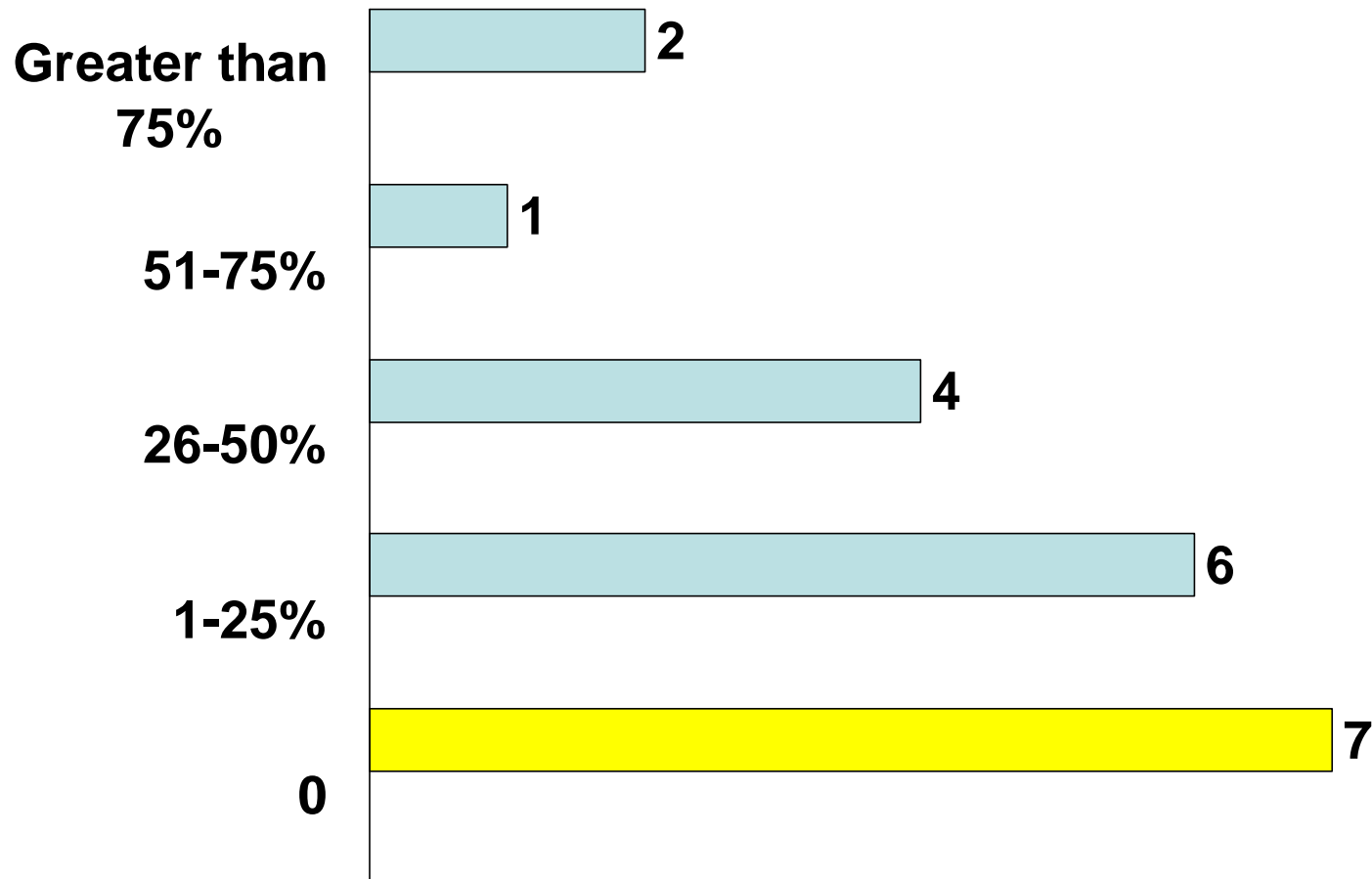
How Often Firms Submitted 510(k)s for Changes to their Products



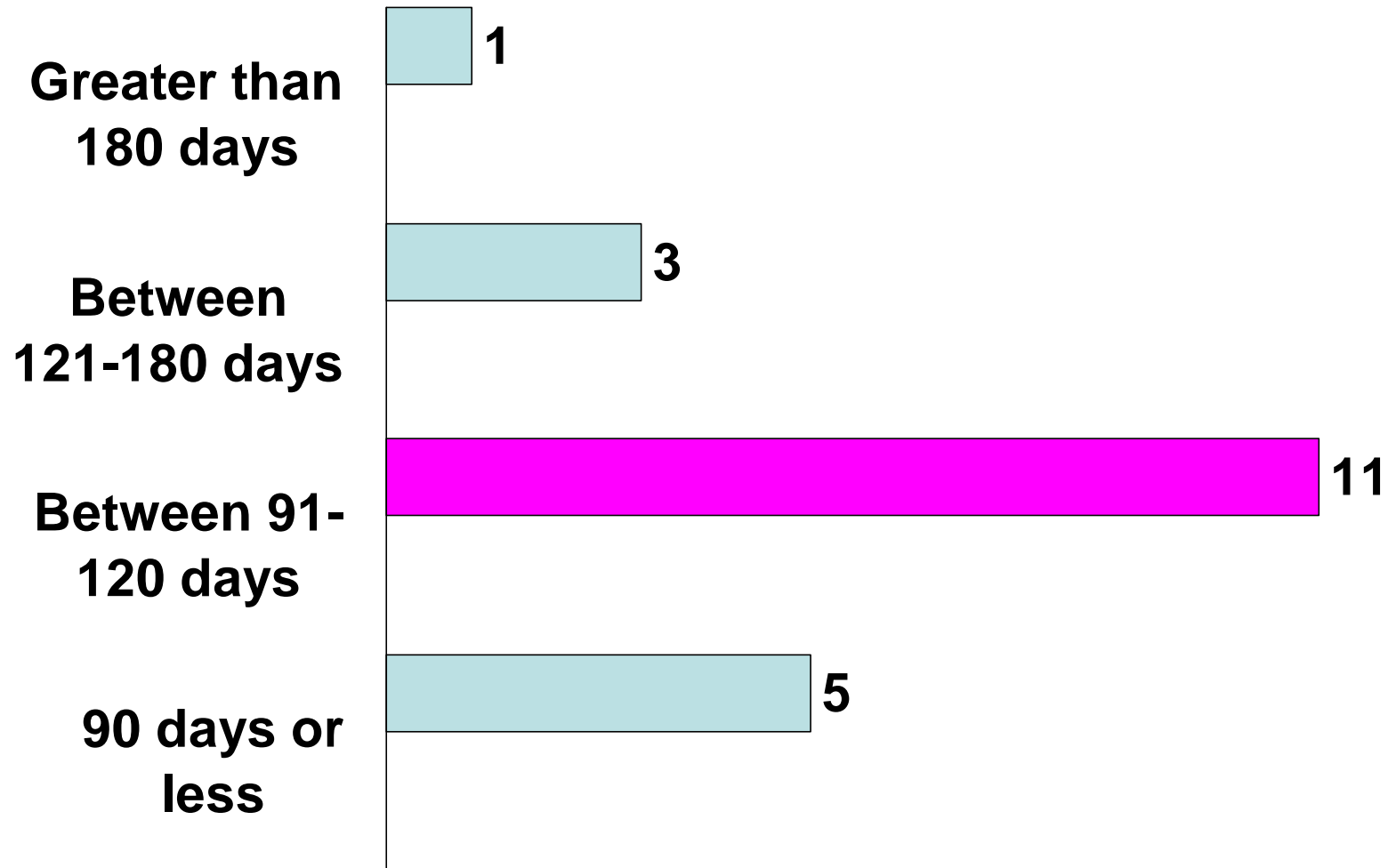
Number of Submissions in the Last 3 Years



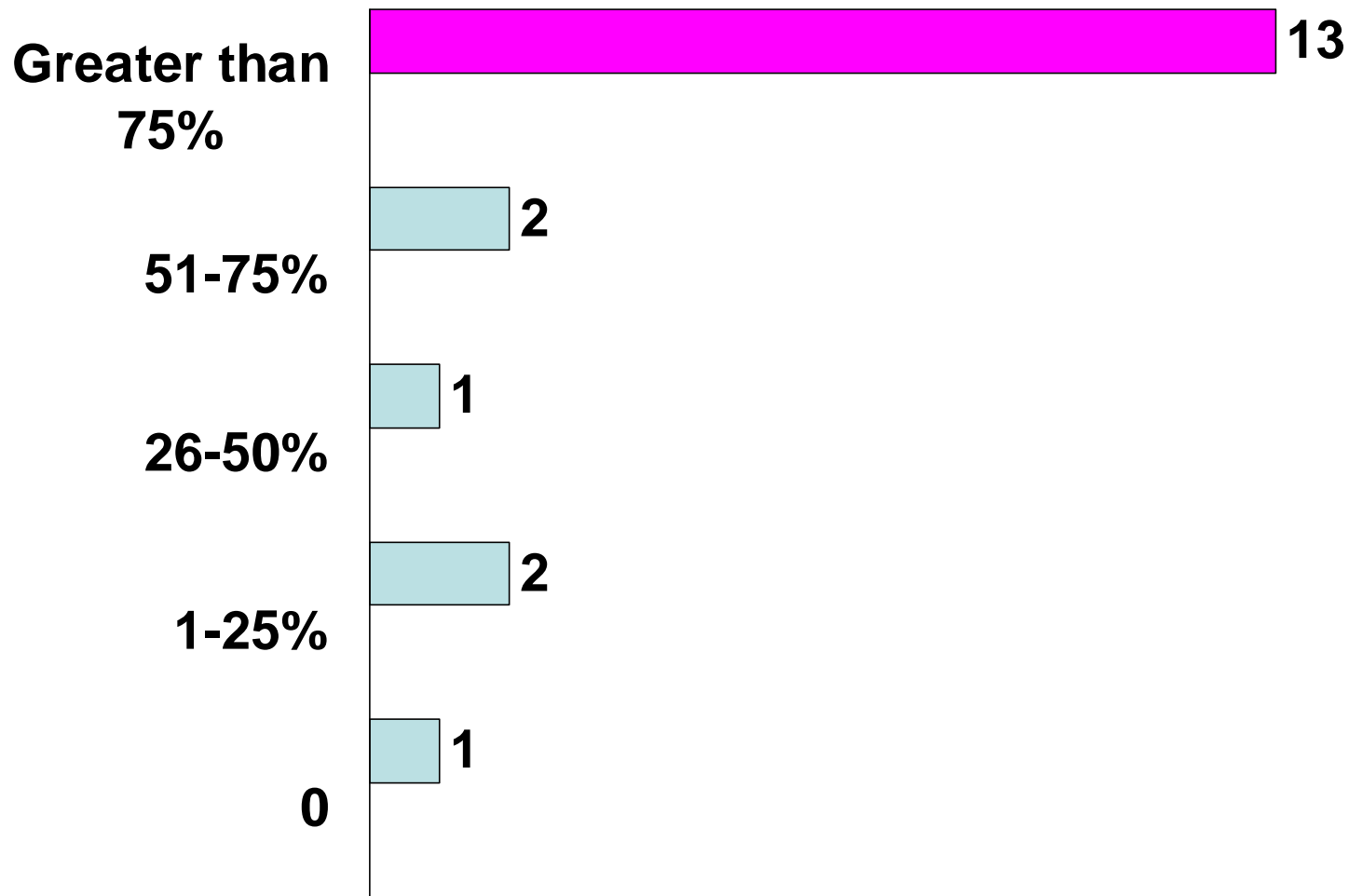
Percent of Submissions Where FDA Didn't Ask for Additional Data



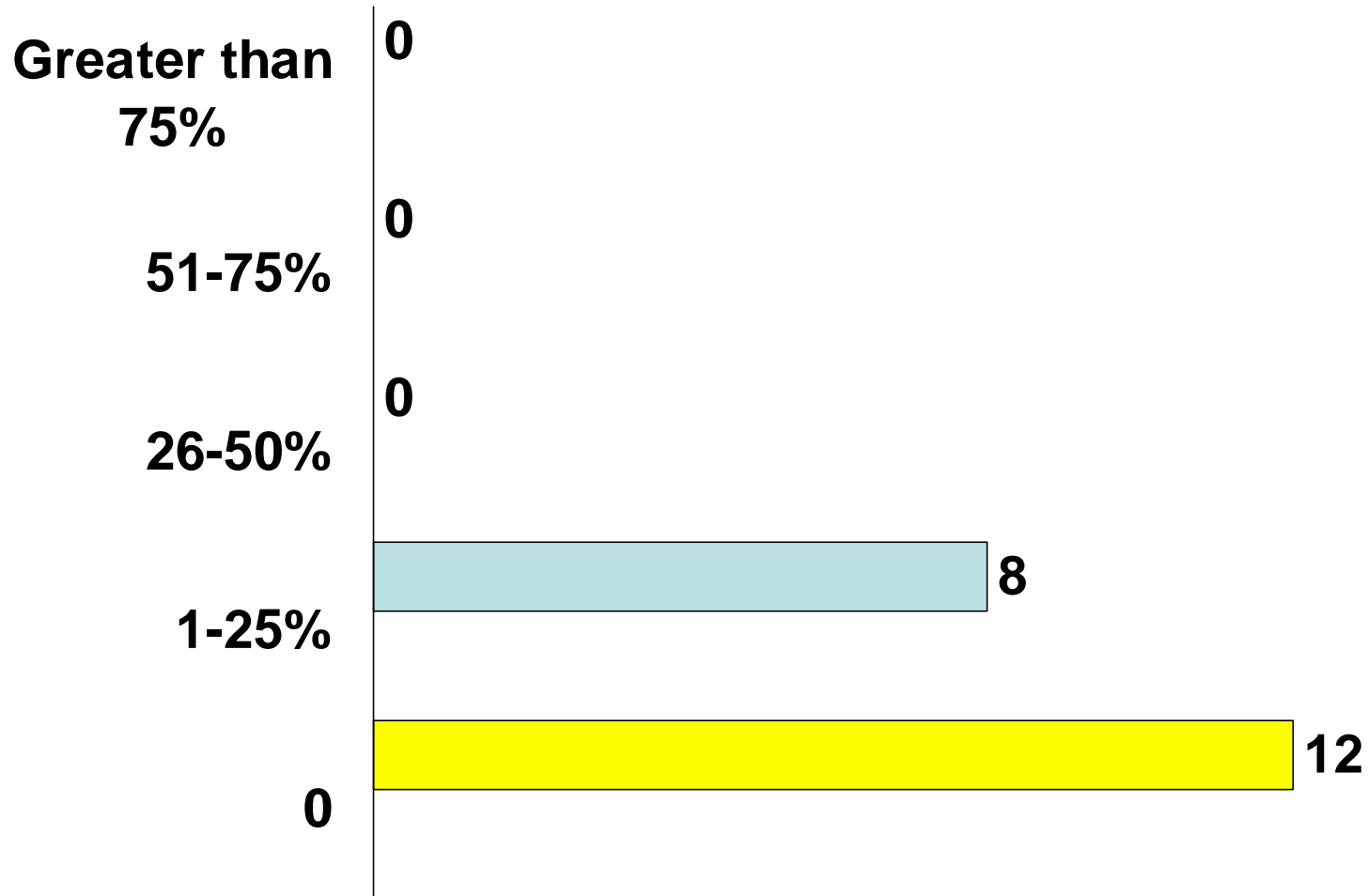
Time from 510(k) Submission to Receiving a Clearance



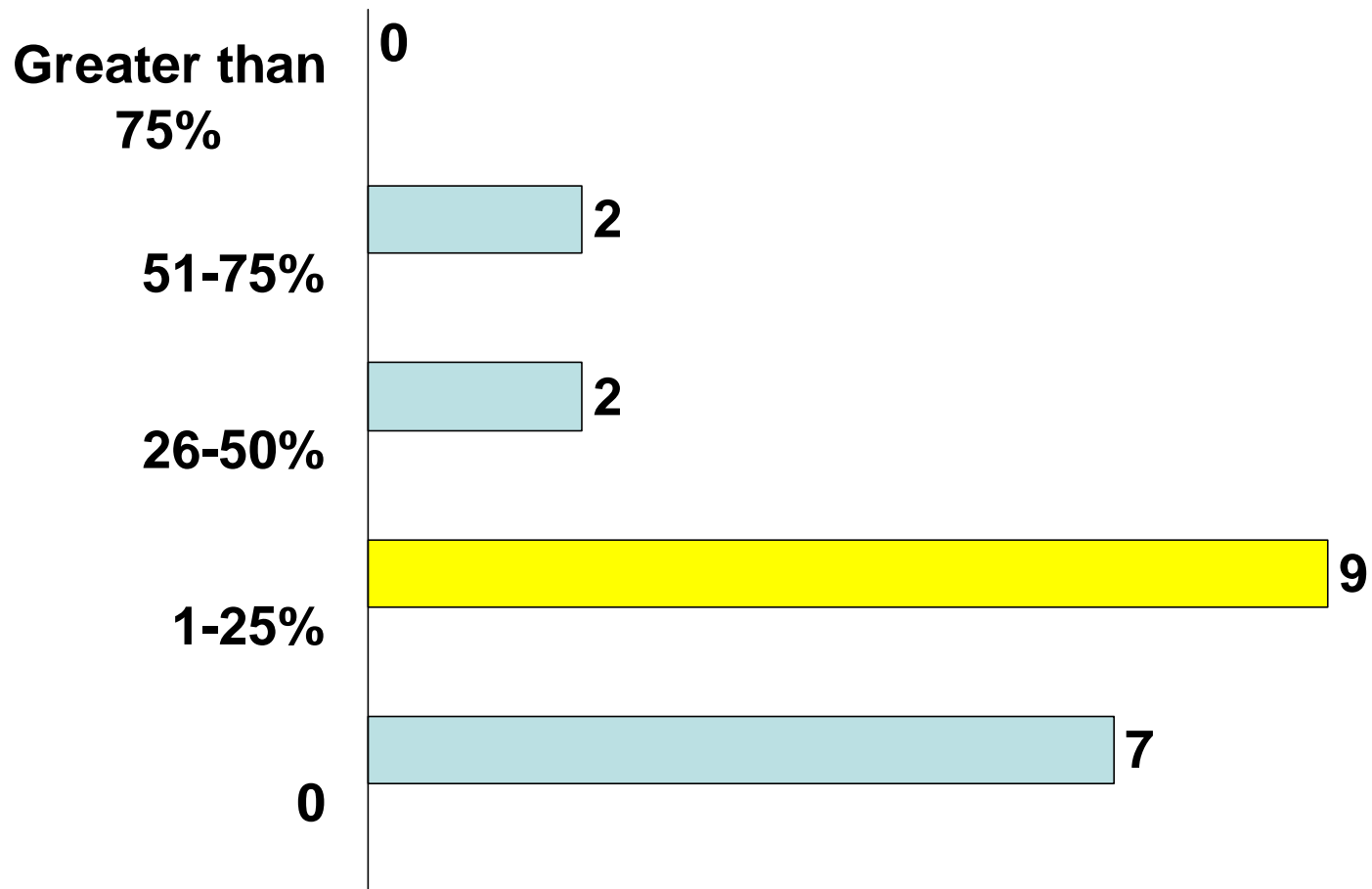
In the past 3 years, the percentage of 510(k) submissions that were “Traditional”



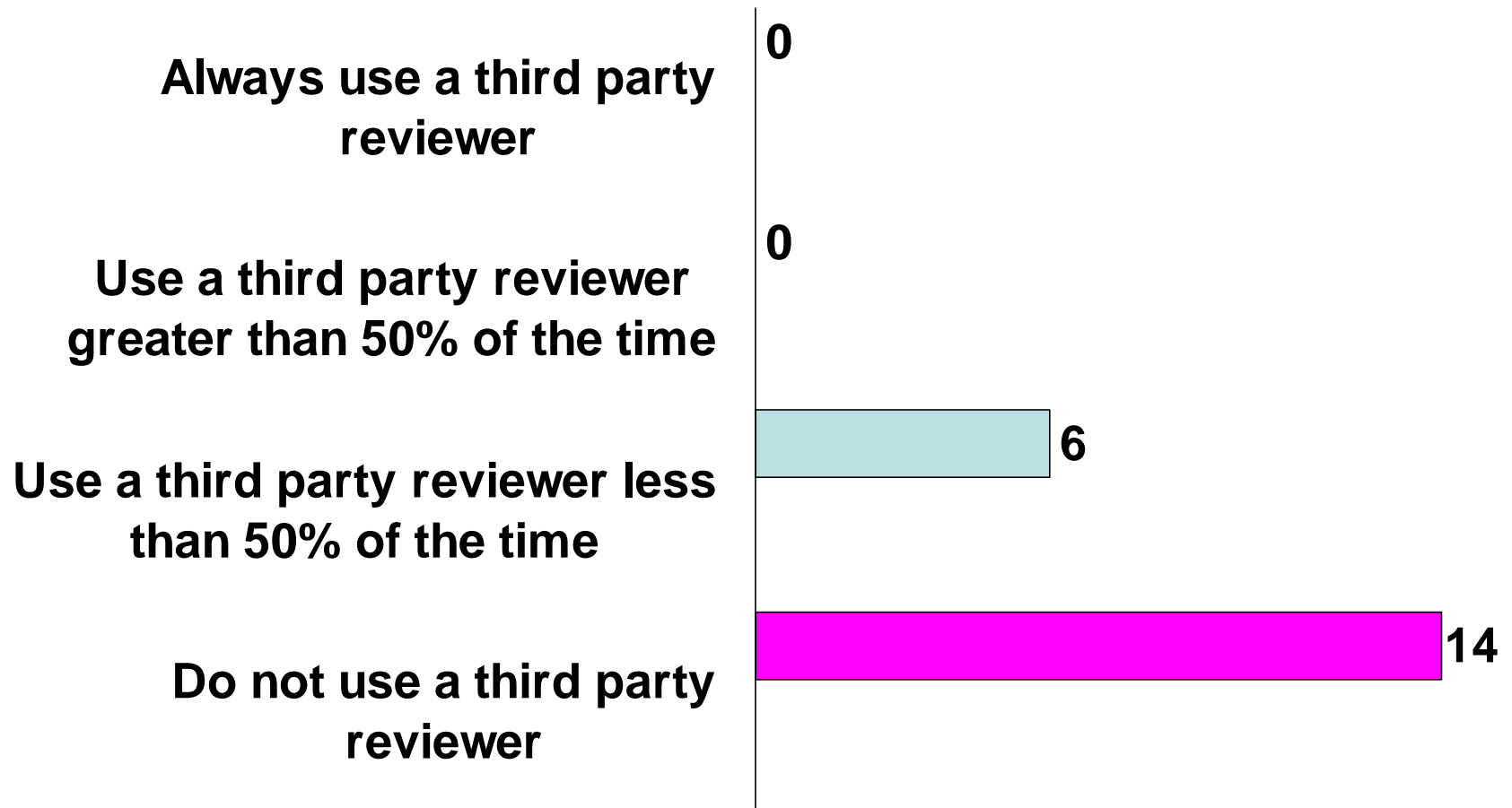
In the past 3 years, the percentage of 510(k) submissions that were “Abbreviated”



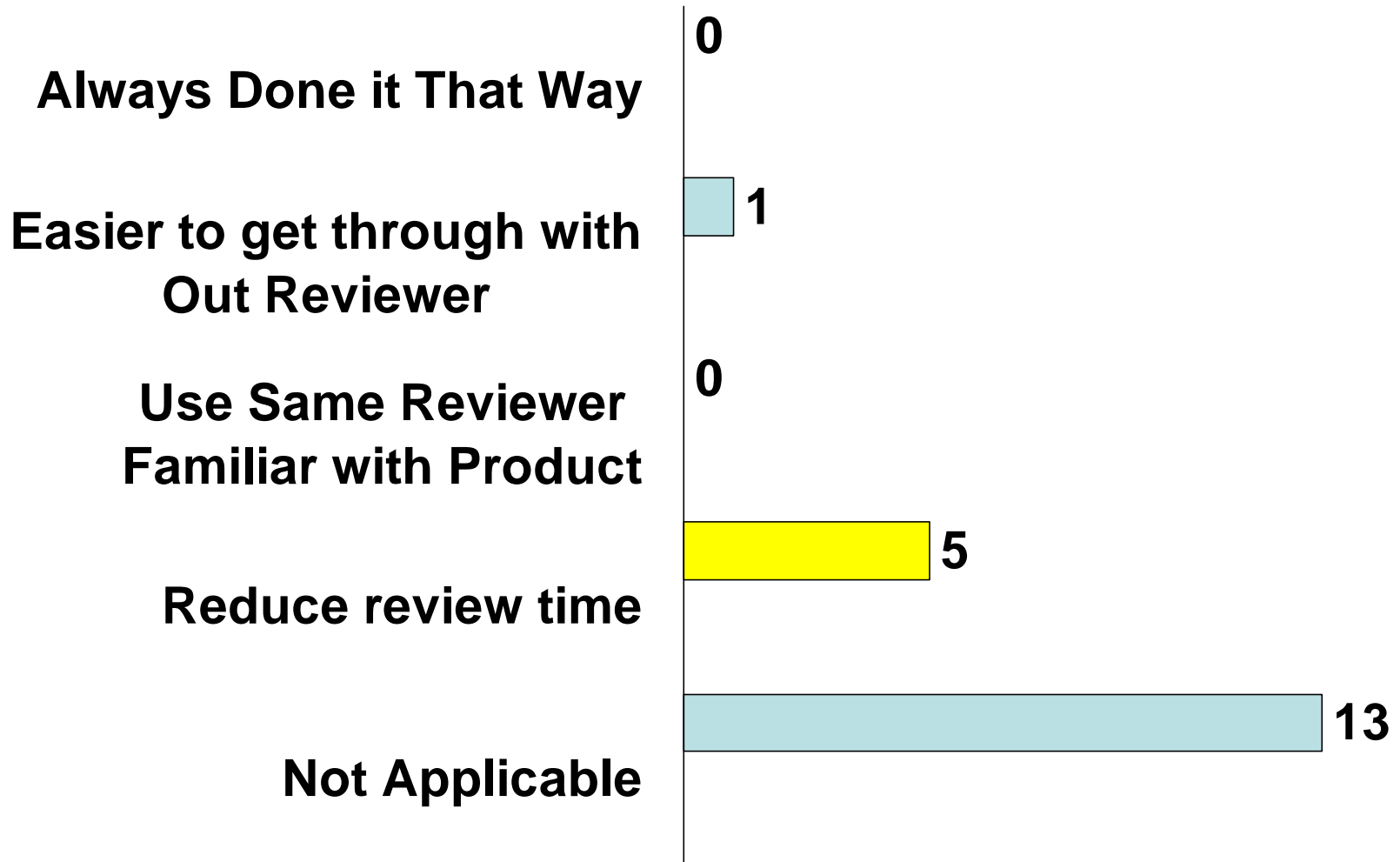
In the past 3 years, the percentage of 510(k) submissions that were “Special”



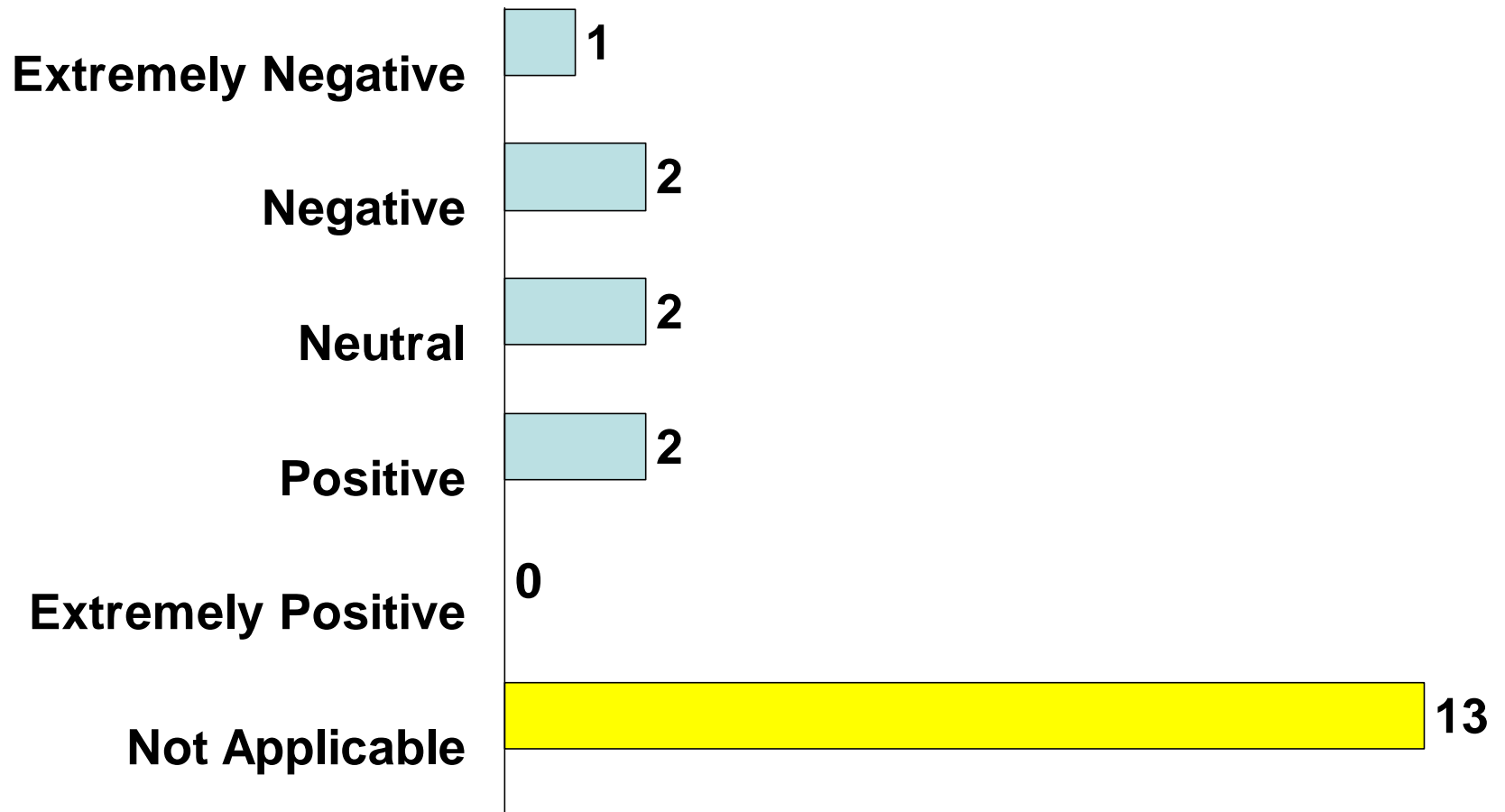
How Often Third Party Reviewers Are Used for 510(k) Submissions



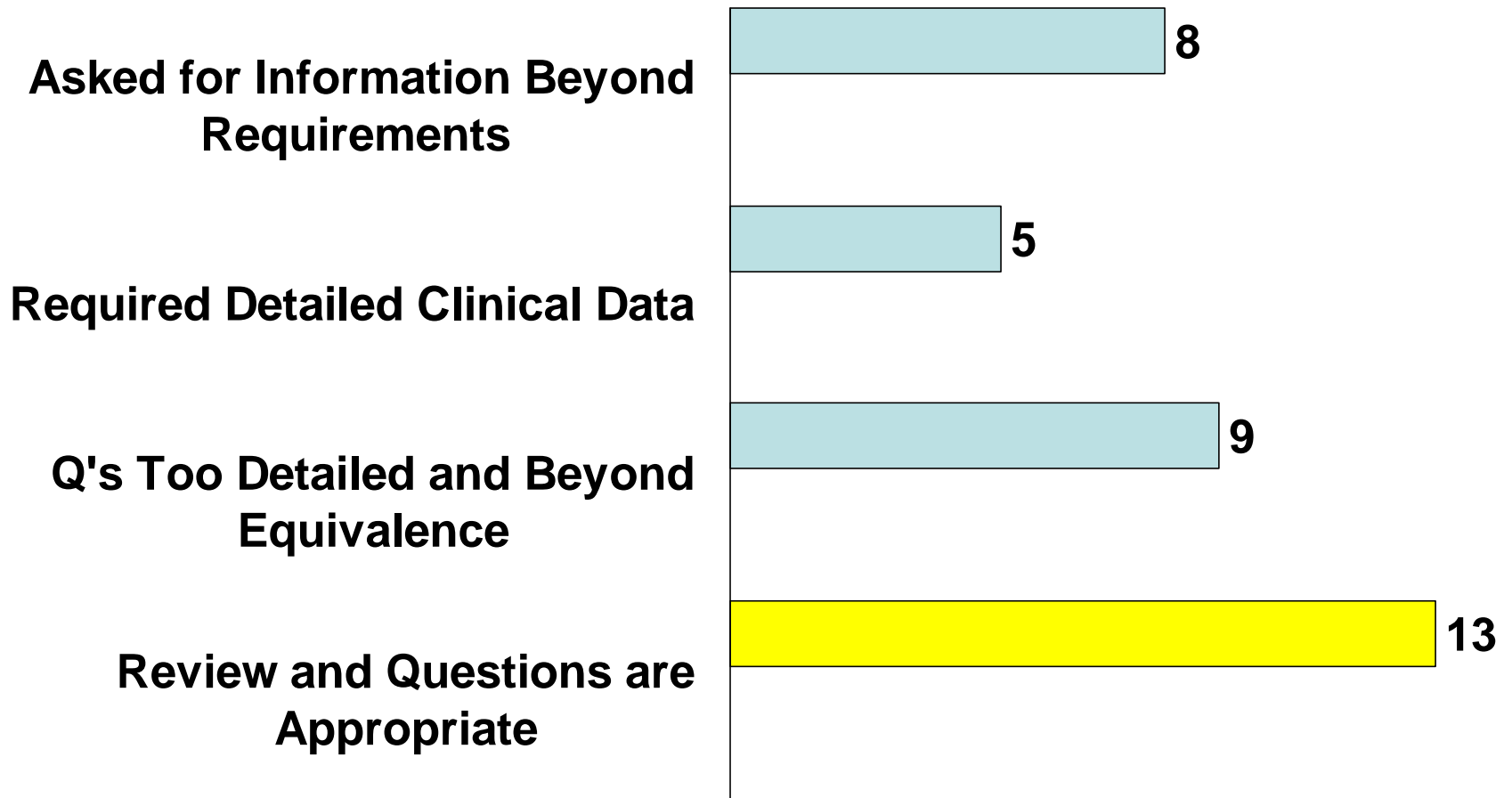
Primary Reason for Using a Third Party Reviewer



Experience Using a Third Party Reviewer

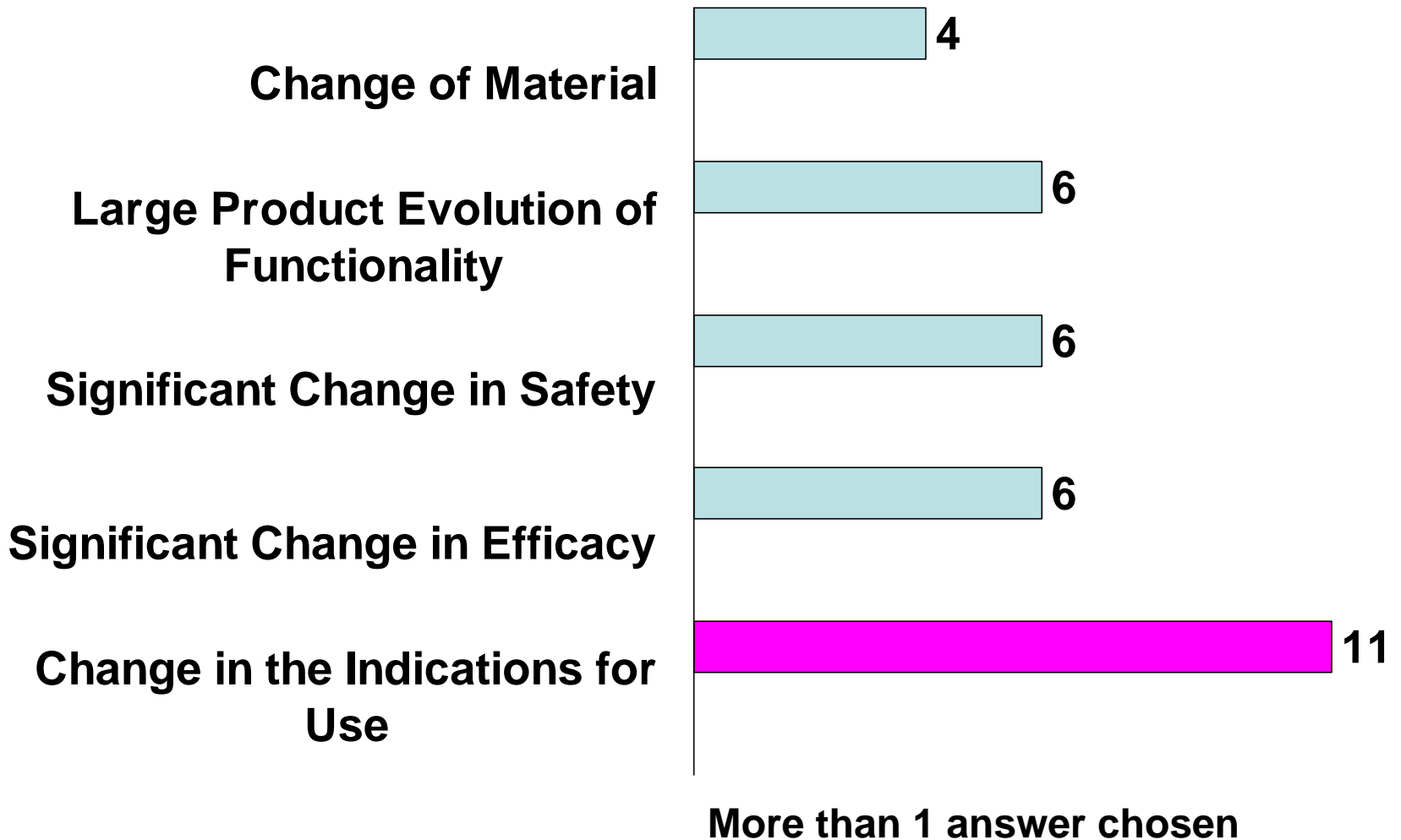


Firms' Experience with FDA Review Process

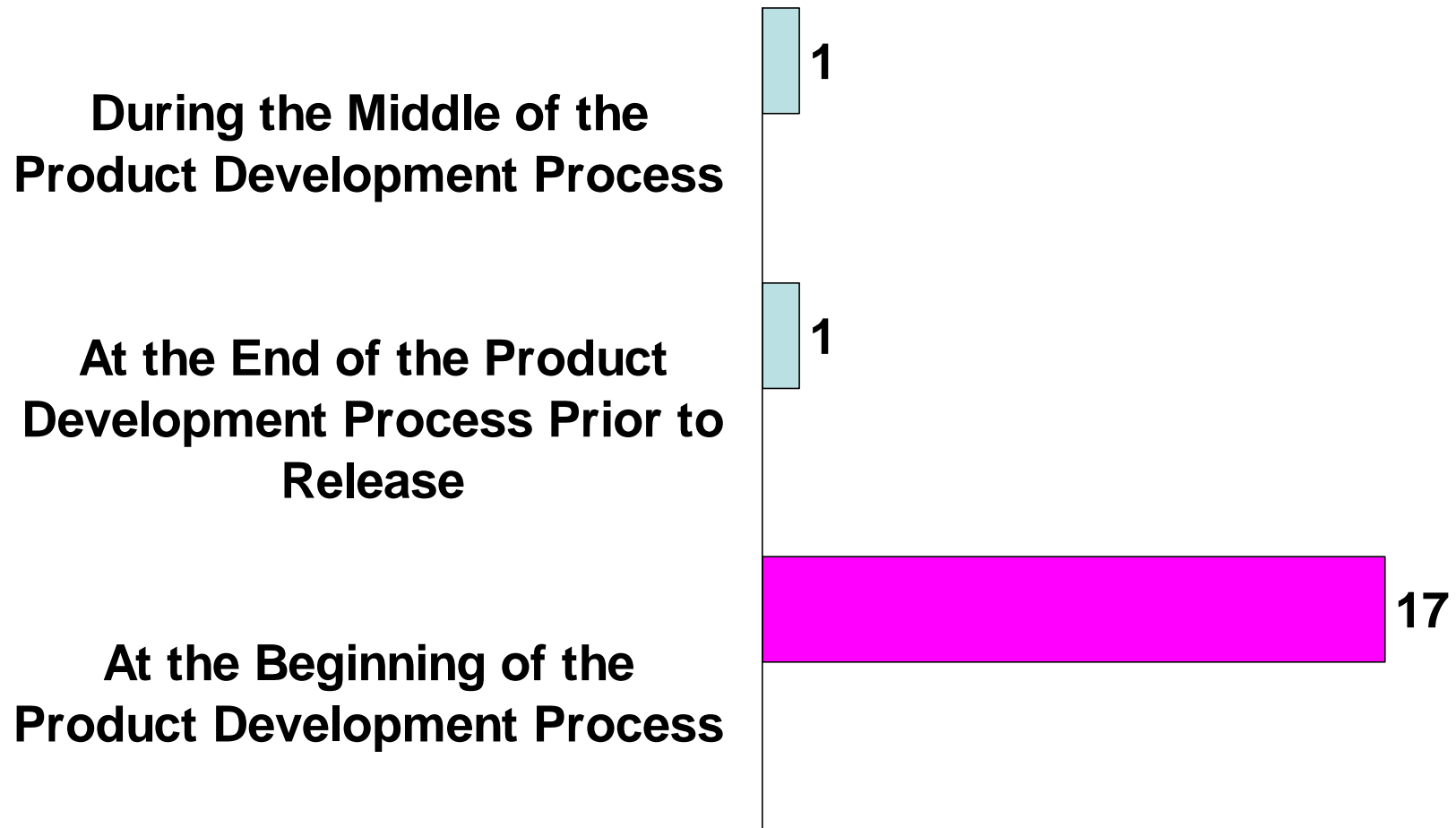


More than 1 answer chosen

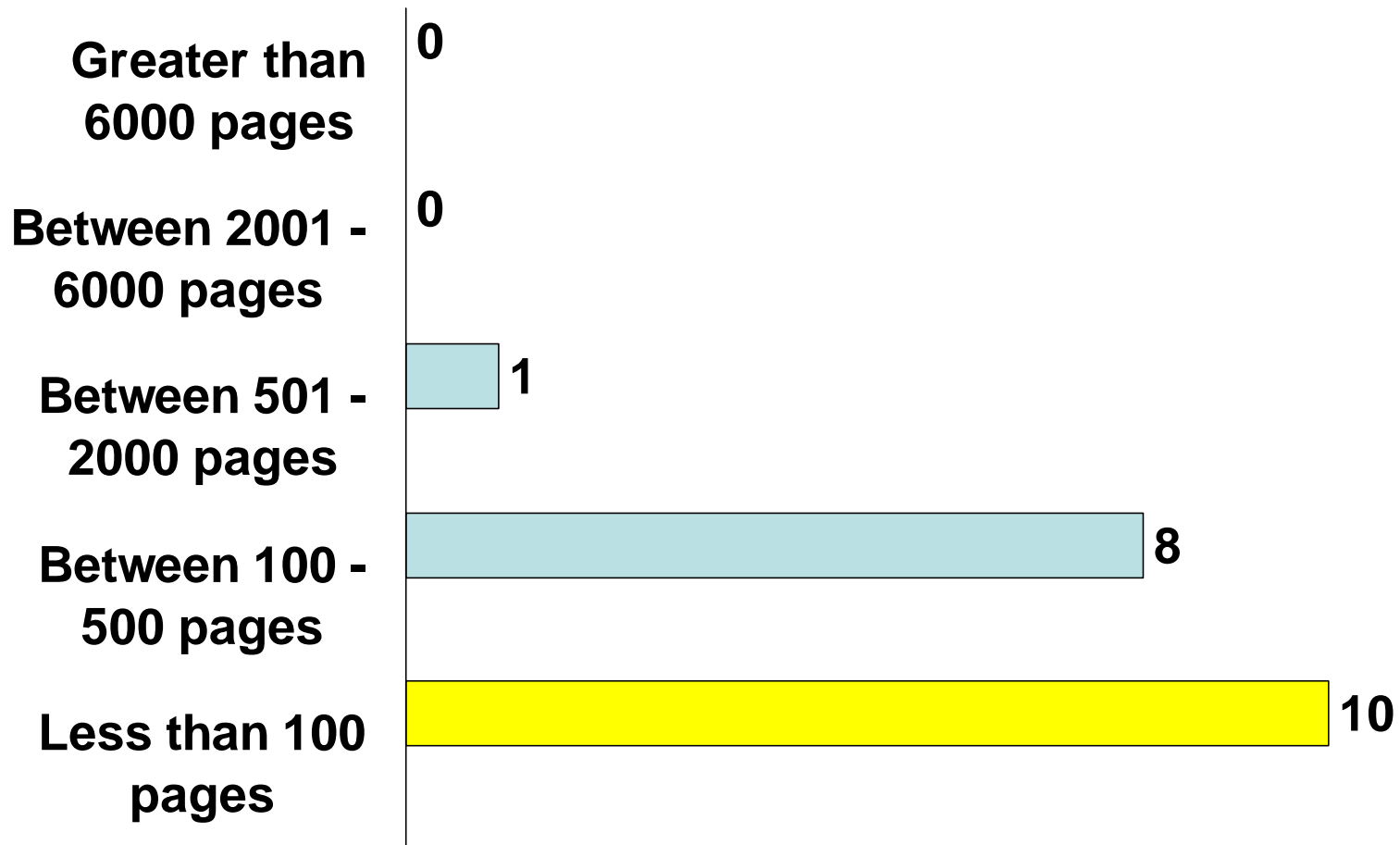
Circumstances When Firms Submitted a New 510(k) for a Device Modification



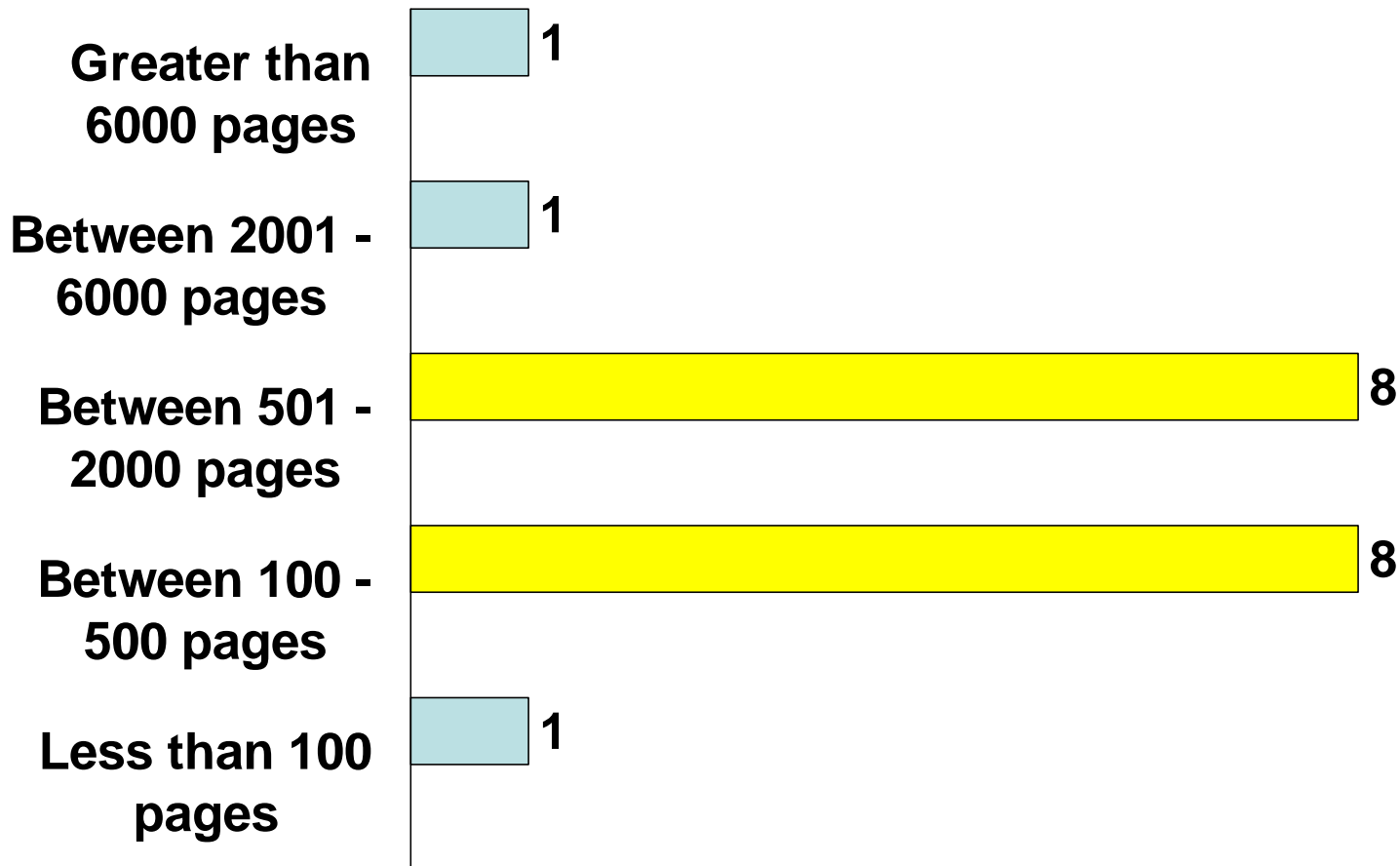
When Firms Addressed the Need for a New 510(k) for New Product Releases



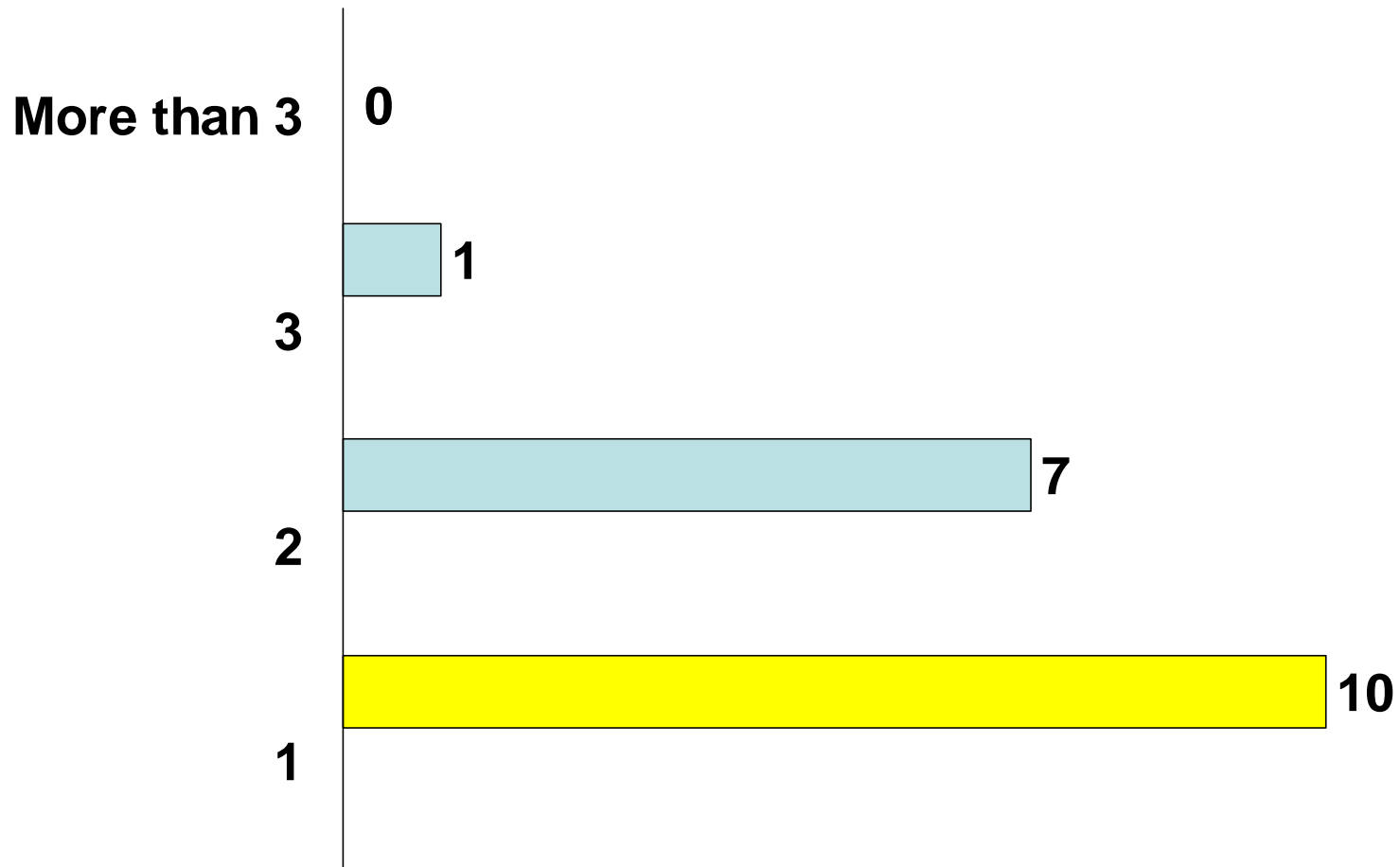
Number of Pages for 510(k) for Least Complex Product Line



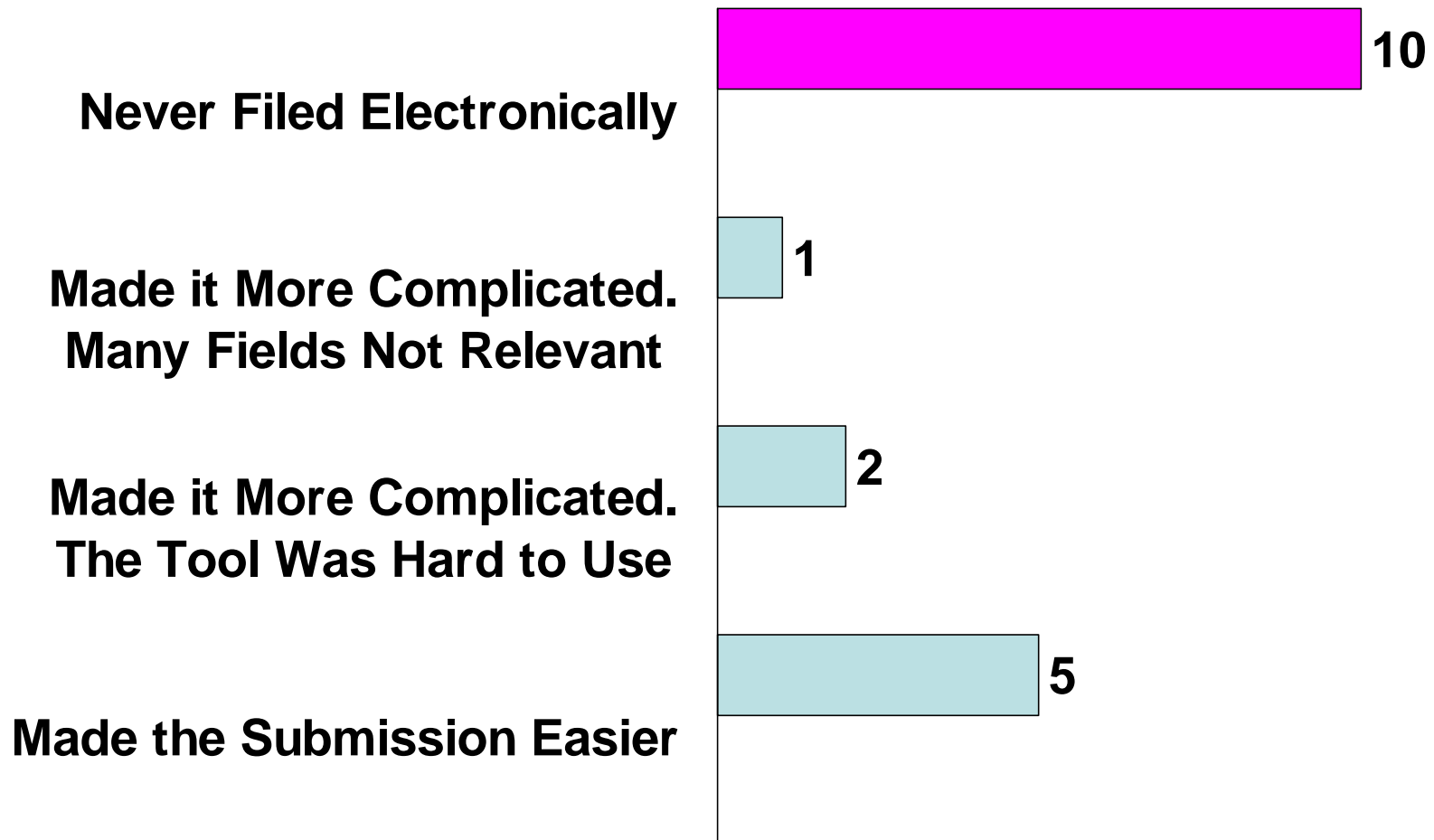
Number of Pages for 510(k) for Most Complex Product Line



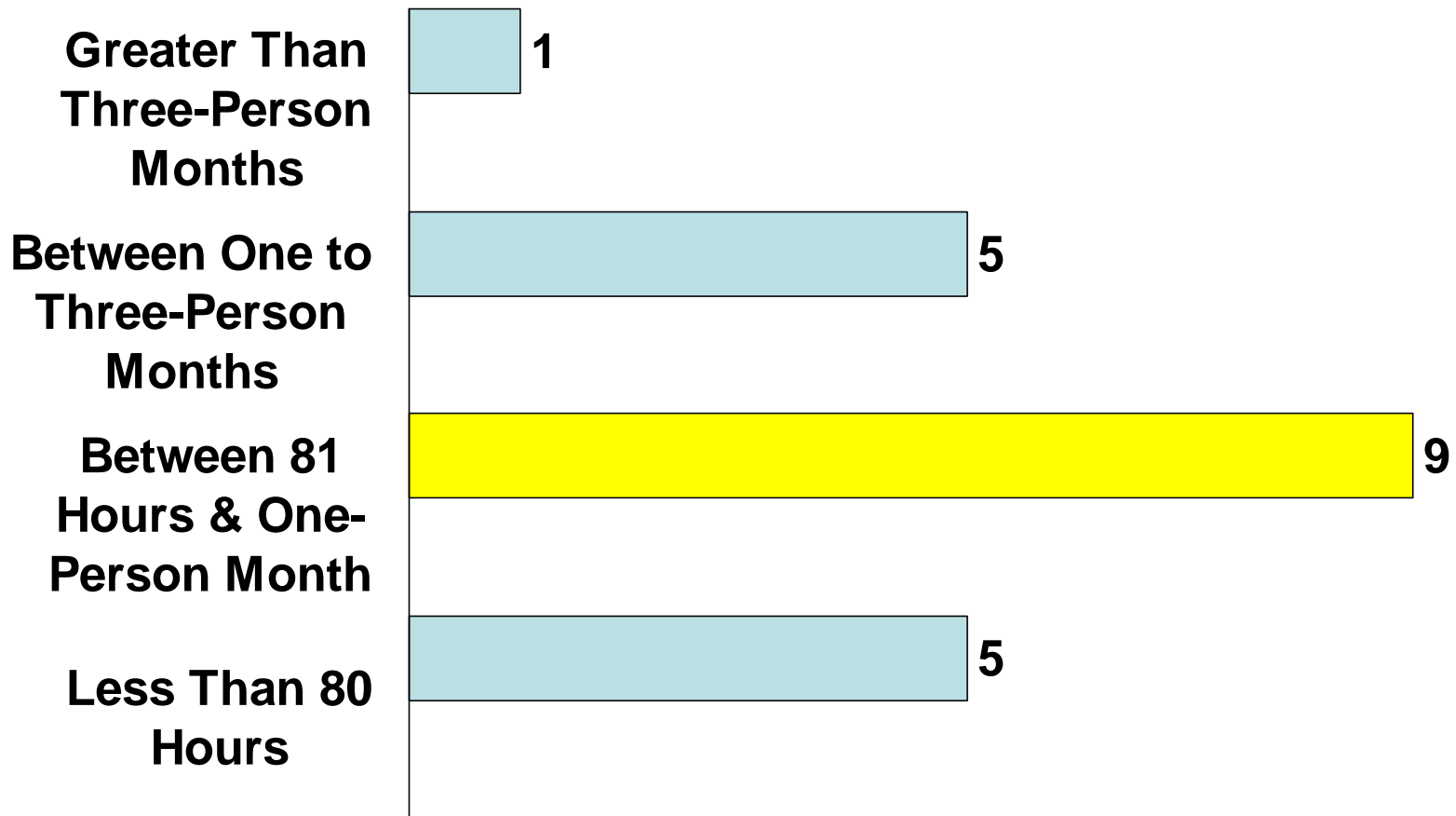
Number of Predicate Devices Used for Comparison in 510(k)



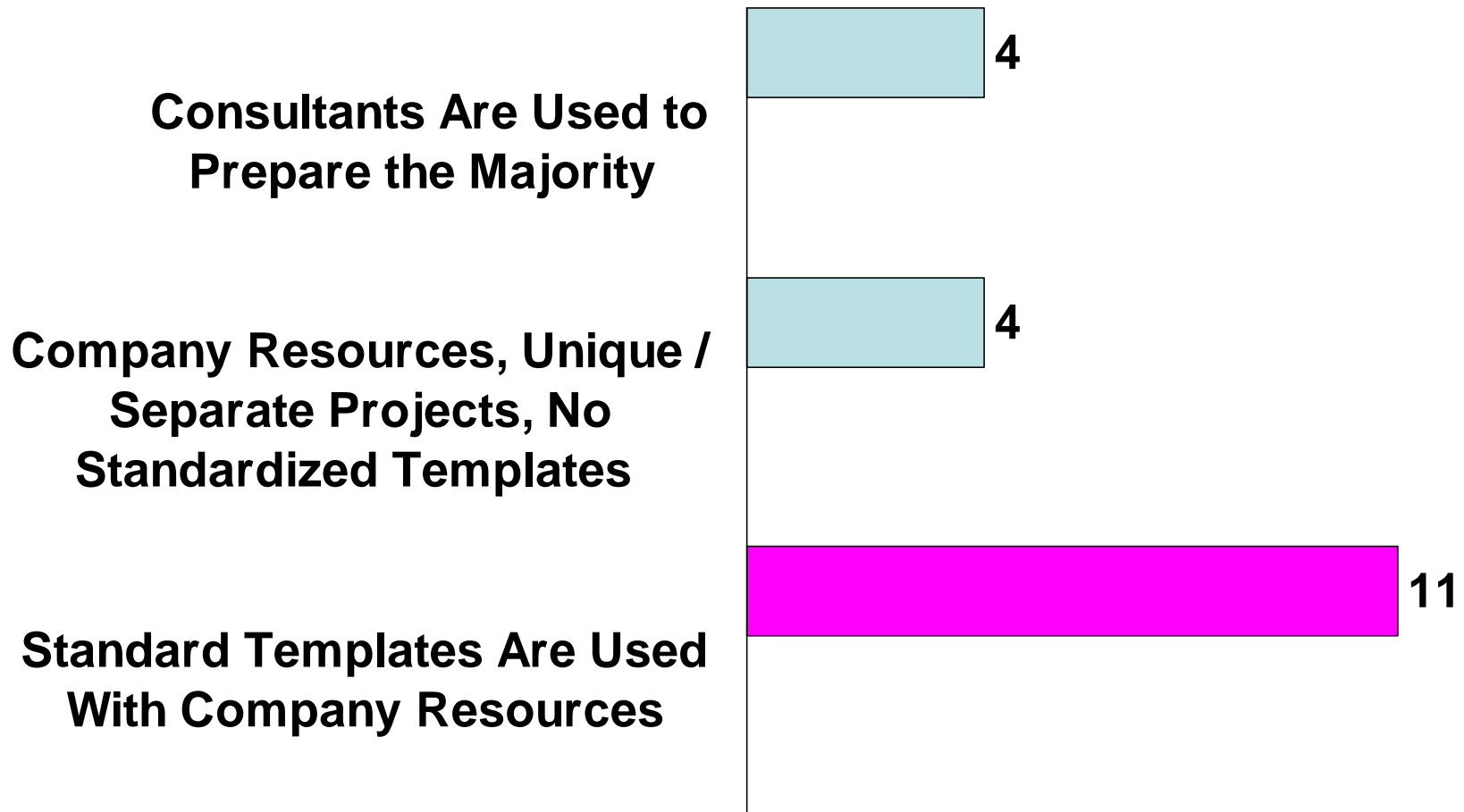
Firms Using FDA's Automated Tools for Electronic Submission of a 510(k)



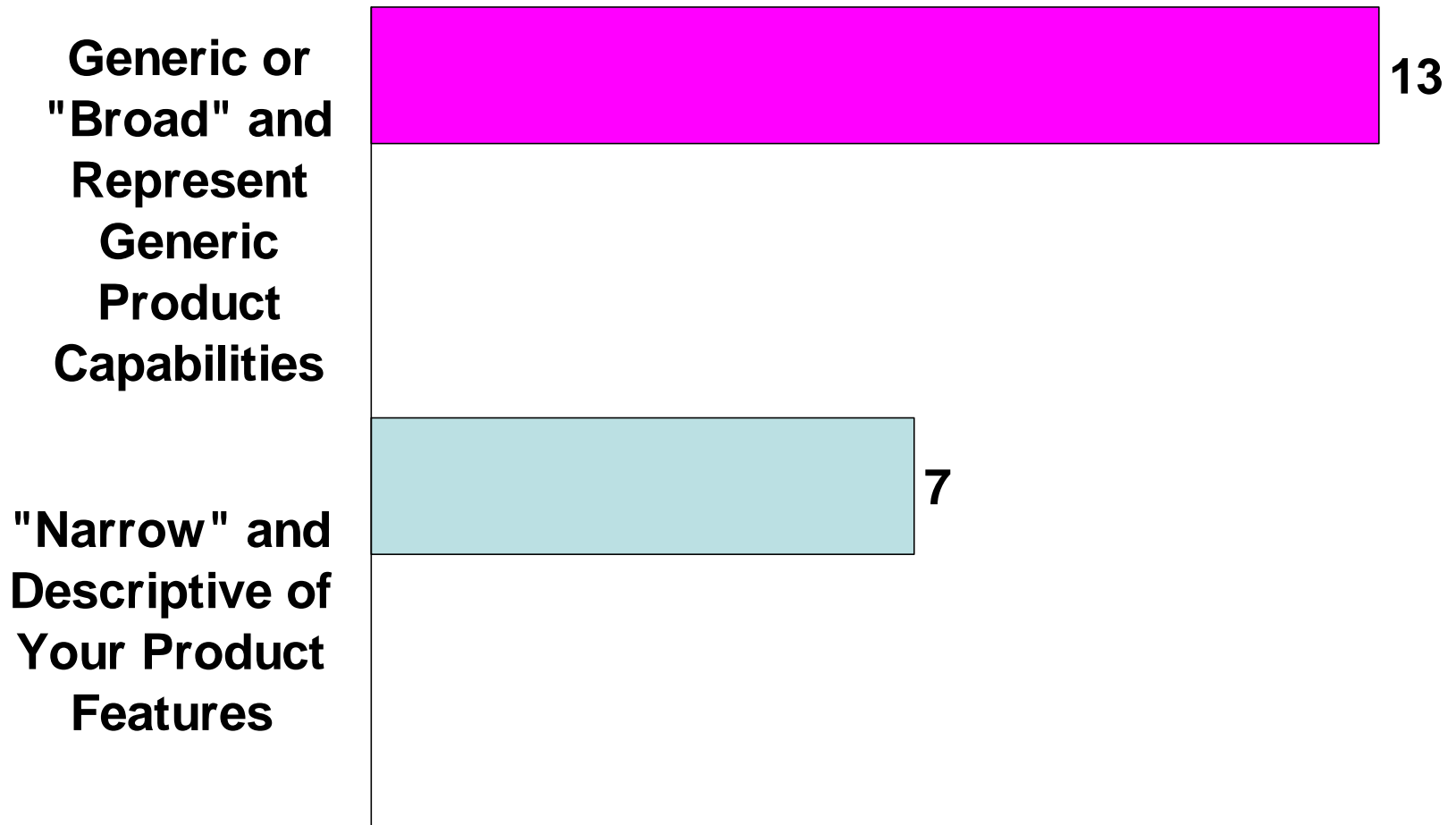
Effort/Time Required to Prepare a 510(k) and Support Responses to Questions



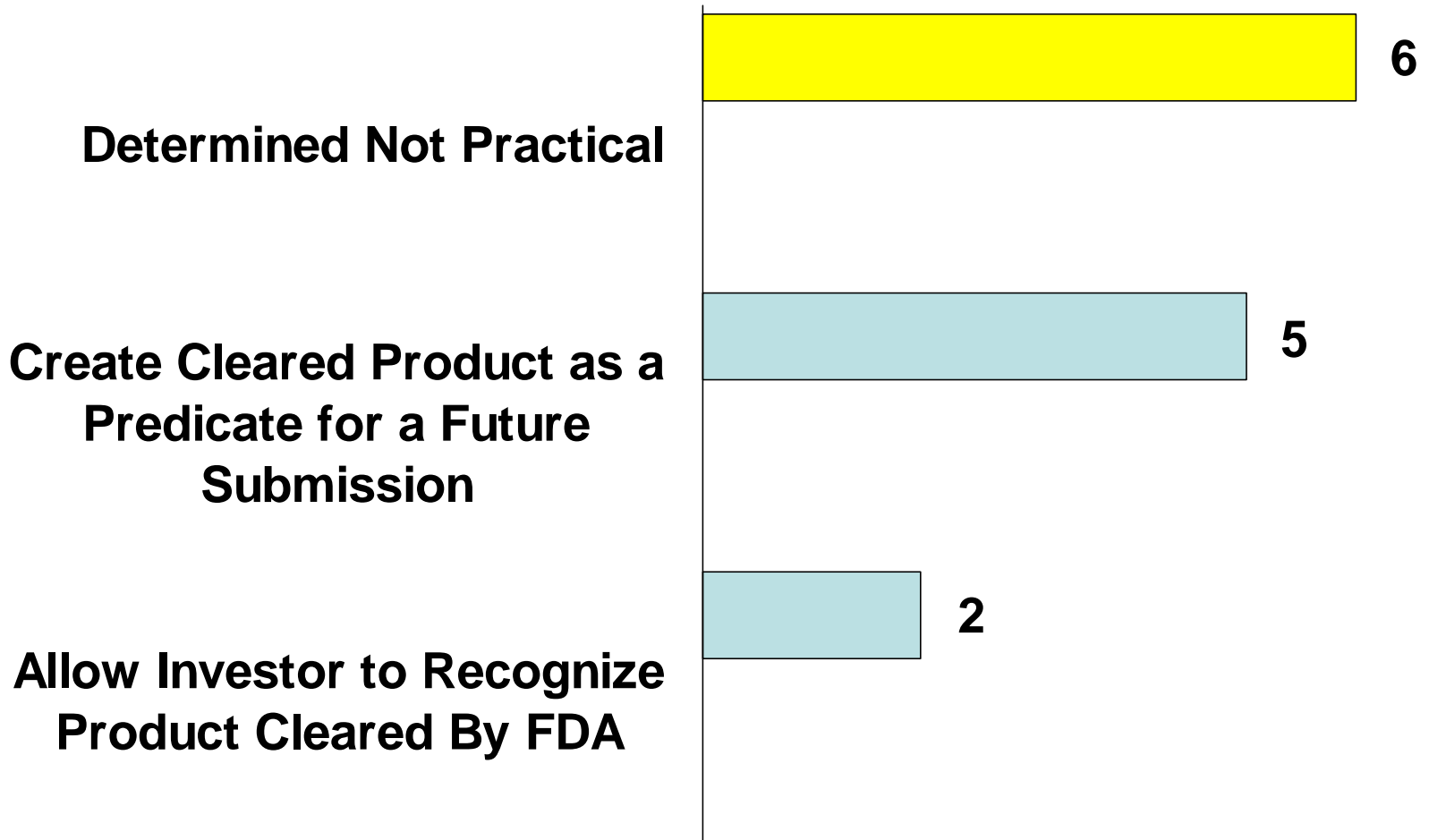
How Firms Prepared their 510(k) Submissions



Approach to Defining the 510(k)s' Indication for Use



Reason that Product Subject to 510(k) Submission Was Not Marketed



How FDA 510(k) Process Compares With Clearance Used By Other Countries (CE Mark, etc...)

